



Infected Blood Inquiry

# The Report

## What happened and why?

- Blood Transfusion: Clinical Practice
- Screening
- Lookbacks
- Public Health
- vCJD

5 of 7

20 May 2024  
HC 569-V

Infected Blood Inquiry

# **The Report**

Presented to Parliament pursuant to section 26 of the  
Inquiries Act 2005.

20 May 2024  
HC 569-V



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## 5.1 Blood Transfusion: Clinical Practice

There are always risks associated with blood transfusions. This chapter examines practices in relation to transfusion that increased the risks of transmission of viral infections and steps that could have been taken to reduce those risks earlier than they were.

### Key dates

**1949** *Notes on Transfusion* by Ministry of Health warns of risks of transfusion.

**1951** Professor Patrick Mollison publishes a textbook known as the bible of blood transfusion, which states that “*transfusion carries risks which are large*”.

**1952** WHO report warns of the dangers of serum hepatitis and warns against non-essential transfusions.

**early 1970s** Dr Cash recommends a “*conservative approach*” to blood transfusion to reduce post-transfusion hepatitis.

**1983** Mollison’s textbook suggests that unnecessary “top up” transfusions are administered to women.

**1984** recommendation that HTCs should be established – by **1994** fewer than 50% of hospitals in England and Wales have an HTC.

**1987** establishment of JPAC to advise the medical directors of the four blood services and prepare guidelines on blood transfusion.

**1989** Professor Contreras publishes *New Trends in Blood Transfusion*, advocating a more rational use of blood.

**1996** SHOT is created to analyse information on transfusion reactions and adverse events.

**1998** UK-wide Better Blood Transfusion initiative starts.

**2001** second Better Blood Transfusion conference.

**2008** SaBTO is created to provide independent advice on the safety of blood, cells, tissues and organs from transfusion/transplantation to all UK health ministers and health departments.

### Abbreviations

**HTCs** hospital transfusion committees

**JPAC** Joint United Kingdom Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee

**MBOS** maximum blood ordering schedules

**RTC** regional transfusion centre

**SaBTO** Advisory Committee on the Safety of Blood, Tissue and Organs

**SHOT** Serious Hazards of Transfusion scheme

## Introduction

It has long been understood within the medical profession that the administration of blood is not without risk: “*there are no therapeutic roses without thorns*”.<sup>1</sup> It was authoritatively being said by 1952 that “*the dangers of serum hepatitis are not appreciated by many sections of the medical profession*” and that “*many non-essential transfusions of blood and plasma are given*.”<sup>2</sup> Recalling the 1970s and 80s, Dr Archibald Prentice said: “*I always preferred not to give blood or blood product if it could be avoided. I was taught that a pint of blood is a potential biological time bomb. One can never be sure of all consequences however safe a blood product is made*.”<sup>3</sup>

Yet, despite the knowledge of the risks of viral infection arising from blood transfusion, in the UK in the 1970s and 1980s blood was often administered by clinicians without a detailed consideration of the risk to patients of transfusion-transmitted infections. The evidence of patients, clinicians and academics, as well as contemporaneous documents demonstrates that from the 1970s to 1990s in Northern Ireland, Wales, Scotland and England blood was given to some patients unnecessarily. Either a transfusion was not strictly medically required, or patients were given more blood than was necessary.

Although textbooks, medical education, articles and clinical guidelines emphasised the need for caution, this was not generally the reality on the ground. Some specialisms were (wrongly) particularly enthusiastic about giving blood to patients – the practice of “topping up” women after labour with one or two units of blood was not only contrary to the relevant guidelines but was also ineffective. A similar practice was deployed by some surgeons.

Decisions about reducing the use of blood often focused on the fact that blood was a scarce resource, given altruistically and not to be wasted. Prior to the emergence of HIV, questions generally centred on issues of blood-type incompatibility and other complications arising from transfusions<sup>4</sup> rather than the risk of viral infection, which was perceived to be

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- 1 According to Dr John Cash, then deputy director of the Edinburgh and South East Scotland Blood Transfusion Service: Cash *Principles of Effective and Safe Transfusion* Proceedings of the Royal Society of Edinburgh 1971/72 p5 PRSE0002637
  - 2 World Health Organization Expert Committee on Hepatitis First Report March 1952 p17 RLIT0000215. The full quotation reads: “*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*”.
  - 3 He said “*I knew the risk of Hepatitis B as I was exposed to it as a Senior Registrar. A contaminated bag of platelets from a Hep B positive donor had burst ... in the late 1970s ... One of my colleagues had been sprayed by plasma from a Hepatitis B positive patient and became very sick with Hepatitis B.*” Written Statement of Dr Archibald Prentice para 25, para 44, para 52 WITN5422001. Dr Prentice worked at Plymouth before moving to the Royal Free in 2006. He was President of the British Society of Haematologists from 2002-2004, and later President of the Royal College of Pathologists 2011-2014.
  - 4 Such as transfusion-related acute lung injury, circulatory overloading, febrile reactions, embolism or allergic reactions.

a smaller risk.<sup>5</sup> Although a minority of clinicians pressed for a reduction in the use of blood transfusion,<sup>6</sup> they did not reflect mainstream medical practice and the administration of blood was (wrongly) seen by many to be low or no risk.

It took until 1998, with the creation of the Better Blood Transfusion initiative, for a UK-wide framework addressing the best practice for blood transfusion to be established and a concerted effort to be made to reduce unnecessary blood transfusions. Professor Michael Murphy of NHS Blood and Transplant (“NHSBT”) has been professor of blood transfusion medicine at the University of Oxford since 2004 and told the Inquiry that there is no formal definition for “*best transfusion practice*” but that it means “*patients should only be transfused when the benefits outweigh the risks, and that alternatives to transfusion should be considered and used where appropriate.*”<sup>7</sup>

Since the risks of blood transfusion were known far earlier, there does not appear to be any good reason why it took so long before coordinated action was taken.

Prior to the Better Blood Transfusion initiative in 1998, some work was introduced in the early to mid 1990s probably in response to a high level of transfusion errors involving blood transfusions of incompatible blood groups causing morbidity and mortality.<sup>8</sup> There was also a changing legislative landscape following the establishment of the Consumer Protection Act 1987 and the introduction of the European Directive on blood, which led senior individuals working in the transfusion services to focus on the issue of blood transfusion.<sup>9</sup> The emergence of variant Creutzfeldt-Jakob disease (“vCJD”) reinforced the need for vigilance.<sup>10</sup>

The steps that were initially taken included audits of blood usage, the creation of “maximum blood schedules”, the engagement of specialist transfusion practitioners and the establishment of hospital transfusion committees (“HTCs”). In 1996 the Serious Hazards of Transfusion scheme (“SHOT”) was created, initially as a voluntary scheme, and quickly demonstrated a need for an improvement in standards for safe and effective blood transfusions.

It appears that there was a level of complacency about the safety of blood resulting in measures not being taken earlier throughout the UK to improve the overall safety of blood transfusions. It is clear had such measures been taken earlier, it is likely that lives would have been saved.

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5 Dr Jonathan Wallis described how: “*Although viral infection remained a serious concern to all in the field of transfusion, other risks of blood transfusion were more prevalent and in terms of early mortality, more pressing.*” Written Statement of Dr Jonathan Wallis para 158 WITN6982001

6 For example David Paintin and Professor Philip Steer. Written Statement of Professor Philip Steer pp5-6 WITN6977001

7 Written Statement of Professor Michael Murphy para 65 WITN7001001

8 Written Statement of Professor Michael Murphy para 91 WITN7001001

9 See for example: Letter from Geoffrey Schild to Dr William Wagstaff 24 February 1987 NHBT0000127\_002, Written Statement of Dr William Wagstaff para 293 WITN6988001

10 Letter from Sir Kenneth Calman to Pauline Banks 1 June 1998 p1 NHBT0015864\_001



## What guidelines were available to clinicians?

From as early as March 1949, the Ministry of Health published *Notes on Transfusion for House Officers*, informing clinicians – in bold text – that plasma or serum should not be given to patients “*unless the advantages to be gained by its transfusion outweigh the risks of transmitting homologous serum jaundice*”. It also states that: “*Ideally, no major surgical procedure should be carried out unless the haemoglobin is within normal limits.*”<sup>11</sup> In the 1954 edition of *Notes on Transfusion*, the bold text warning of the risk of jaundice and the advice about benefits outweighing risk was removed. There is no explanation within the text for this change. Instead, at the start of the booklet, it says: “*A transfusion should never be given without a definite indication.*”<sup>12</sup> The 1958 and 1963 editions reiterate this statement and add that this is in “*the patient’s interests*” and is also because “*supplies of blood are not unlimited and with the ever-growing demand for blood it is imperative that it is not used unnecessarily.*”<sup>13</sup>

In 1951 Professor Patrick Mollison published his textbook which came to be known as the “*bible*’ of blood transfusion”.<sup>14</sup> It stated that, in treating anaemia, it must “*never be forgotten that transfusion carries risks which are large compared with those of conservative treatment.*”<sup>15</sup> In the 1956 edition, Professor Mollison recommended the use of blood rather than plasma when treating an injured patient to reduce the likelihood of anaemia developing: “*Clinical impressions suggest that the haemoglobin concentration should not be allowed to fall below 9 g./100ml ... Evidently this is a minimum. The ideal should be to replace approximately as much whole blood as the patient has lost.*”<sup>16</sup>

The risks of homologous<sup>17</sup> serum jaundice transmissible via blood transfusion were noted in the 1951, 1956 and 1961 editions.<sup>18</sup>

When the Ministry of Health updated their *Notes on Transfusion* in 1958, they recorded that: “*Preferably, no major surgical procedure should be carried out unless the haemoglobin is at least 10.4g. per cent ... If the haemoglobin level cannot be restored by appropriate medical treatment, pre-operative transfusions may have to be given.*”<sup>19</sup>

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11 Ministry of Health *Notes on Transfusion for House Officers* 1949 p4, p7 DHSC0200152

12 Ministry of Health *Notes on Transfusion* 1954 p4 DHSC0200153

13 Ministry of Health *Notes on Transfusion* 1958 p4 WCAS0000008, Ministry of Health *Notes on Transfusion* 1963 p4 JPAC0000162\_021. Both were issued by the Ministry of Health in association with the Scottish Home and Health Department.

14 Written Statement of Professor Dame Marcela Contreras para 42 WITN5711001

15 Mollison *Blood Transfusion in Clinical Medicine* 1951 p48 RLIT0001567

16 Mollison *Blood Transfusion in Clinical Medicine* 1956 p52 RCPE0002067

17 ie from another human being, as opposed to from some other species.

18 Mollison *Blood Transfusion in Clinical Medicine* 1951 p179 RLIT0001567, Mollison *Blood Transfusion in Clinical Medicine* 1956 pp220-221 RCPE0002067, Mollison *Blood Transfusion in Clinical Medicine* 1961 pp290-291 RCPE0002068

19 Ministry of Health *Notes on Transfusion* 1958 p6 WCAS0000008. A similar approach appears to have been taken in the US throughout the same period. Hérbert et al *Review of the clinical practice literature on allogeneic red blood cell transfusion* Canadian Medical Association Journal 1997 p4 RLIT0001025



Dr George Discombe’s 1960 textbook highlighted the danger of hepatitis as one that “*must never be forgotten when assessing the need for transfusion.*” He described the “*very common*” use of blood transfusion for treating pre-operative anaemia as “*inexcusable*”.<sup>20</sup>

In 1963, the *Notes on Transfusion* highlighted that the use of blood transfusion to correct “*moderate or slight degrees of anaemia*” was “*unjustifiable*” where there were slower but safer methods available:

*“A transfusion should never be given without a definite indication; not only is this in the patient’s interest, since an element of risk is associated with every transfusion, but supplies of blood are not unlimited and with the ever-growing demand for blood it is imperative that it should not be used unnecessarily.*

*The use of transfusion to correct moderate or slight degrees of anaemia that could be overcome as effectively, if more slowly, by other means, seems unjustifiable unless some cogent reason for speed of recovery exists. In some instances failure to institute simpler and safer but equally effective treatment earlier leads to the quite unnecessary use of blood transfusion.”<sup>21</sup>*

In 1967, Professor Mollison’s updated book also emphasised that pre-operative transfusions “*could be avoided if it were a routine practice to determine the patient’s haemoglobin concentration at the time when operation is first considered, as there would then more often be time to treat the anaemia with iron, etc.*”<sup>22</sup> Despite this recommendation, the evidence received by the Inquiry suggests that pre-operative iron was not commonplace. In a contemporaneous article, Dr Jean Grant noted that the decision not to give blood required a doctor to have “*the strength of mind to make the unfashionable decision not to transfuse.*”<sup>23</sup>

In the early 1970s Dr (later Professor) John Cash, the then deputy director of the Edinburgh and South East Scotland Blood Transfusion Service, questioned why red cell concentrates were not being used more to release more plasma for use and noted that the medical profession were “*frequently guilty of forgetting those hazards*” of blood transfusion which had “*already been well documented.*” He considered that a “*much more conservative approach*” to blood transfusion could reduce the incidence of post-transfusion hepatitis.<sup>24</sup> Major General Hugh Jeffrey, the national medical director of the Scottish National Blood Transfusion Service (“SNBTS”) also emphasised the need to give a patient “*only those*

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20 Discombe *Blood Transfusion: A Guide to the Practice of Transfusion within Hospitals* 1960 p18, p22 RCSE0000002

21 Ministry of Health *Notes on Transfusion* 1963 p4 JPAC0000162\_021. Emphasis in original. The same text would be in the version published in 1973. Department of Health and Social Security *Notes on Transfusion* 1973 p4 HCDO0000861. Professor Dame Marcela Contreras confirmed that what was set out was nothing new in 1973. Professor Dame Marcela Contreras Transcript 2 December 2021 p151 INQY1000165. The 1973 version was issued by the Department of Health and Social Security with the Scottish Home and Health Department and the Welsh Office.

22 Mollison *Blood Transfusion in Clinical Medicine* 1967 p38 RLIT0001570

23 Grant *Complications of Blood Transfusion The Practitioner* 1965 p8 PRSE0003897

24 Cash *Principles of Effective and Safe Transfusion* Proceedings of the Royal Society of Edinburgh 1971/72 pp5-6 PRSE0002637

*components of blood which he lacks, thus eliminating to a very considerable extent sources of reaction, infection and sensitisation and enabling optimal use of the blood collected.”<sup>25</sup>*

The 1972 edition of Professor Mollison’s textbook stated that before surgery was undertaken haemoglobin should be raised above 10g/100ml, “*even if only trivial haemorrhage is expected*” because there was “*evidence that ... there is some interference with cardiac function*”.<sup>26</sup> This was updated in the 1979 edition to note that although there was some depression of ventricular function with a packed cell volume (“PCV”)<sup>27</sup> of about 30% (corresponding to a haemoglobin level of 10g/100ml):

*“O<sub>2</sub> extraction, central venous PO<sub>2</sub><sup>28</sup> and coronary sinus PO<sub>2</sub> remain unchanged until the PCV is down to about 20% ... It has been suggested that a PCV of 20% or more is acceptable in patients undergoing surgery in civilian practice provided that cardiac, pulmonary, hepatic and renal function are normal and that there is normal blood supply to the brain ... Although most clinicians seem likely to continue to demand that their patients shall have a PCV of at least 30% before undergoing major surgery, it does seem that in healthy young adults there is little need to insist on a higher figure.”<sup>29</sup>*

In the 1983 edition of Professor Mollison’s textbook, post-operative transfusion to “top up” patients was specifically addressed and he noted that a higher percentage of women than men were transfused after an operation involving blood loss “*because there is a tendency to use the same level of haematocrit (or Hb) in women as in men in deciding whether transfusion is required. There would be a substantial saving in blood if the normal difference in haematocrit between men and women were taken into account in deciding the need for transfusion*”.<sup>30</sup>

The 1984 edition of *Notes on Transfusion*, again issued by the Department of Health and Social Security (“DHSS”) with the Scottish Home and Health Department and the Welsh Office for the National Blood Transfusion Service (“NBTS”) and SNBTS, noted a preference for haemoglobin to be 10g/dl before major surgery and made express reference to post-transfusion hepatitis and the risks of Hepatitis B and non-A non-B Hepatitis.<sup>31</sup> It did not contain any reference to HTLV-3 or AIDS. The 1988 *Handbook of Transfusion Medicine* (the postcursor to the *Notes on Transfusion*), referred to assisting clinicians “*to avoid the avoidable risks and to explain those which are unavoidable, so they can be taken into account when clinical decisions are made about transfusion for individual patients.*” It

25 Jeffrey *Modern Transfusion Practice* Health Bulletin May 1976 p2 DHSC0003738\_045

26 Mollison *Blood Transfusion in Clinical Medicine* 1972 p30 RLIT0001573

27 Packed cell volume is the proportion of blood that is made up of blood cells.

28 PO<sub>2</sub> stands for the partial pressure of oxygen and reflects the amount of oxygen dissolved in blood.

29 Mollison *Blood Transfusion in Clinical Medicine* 1979 p34 RLIT0001569

30 Mollison *Blood Transfusion in Clinical Medicine* 1983 pp72-73 RLIT0001571. “Haematocrit” is a measure or calculation of the proportion of blood composed of red blood cells. It differs between men and women.

31 Department of Health and Social Security *Notes on Transfusion* 1984 p12, pp19-20 PRSE0004766. 10g/dl is 10g/100ml.

noted that there was “*little or no firm evidence supporting*” the belief that a perioperative transfusion was required where haemoglobin levels were below 10g/dl. It also provided detailed guidance about different blood components.<sup>32</sup>

Many of the guidelines published during the 1980s focused on issues of blood bank documentation and record-keeping, including by the British Committee for Standards in Haematology, part of the British Society for Haematology.<sup>33</sup> At this time, there was also a shift from materials being produced by either individual clinicians or by government, to guidelines being produced by national bodies to address specific scenarios in particular specialities.<sup>34</sup> Those guidelines tended to give indications for when particular blood components should be used and the levels of, for example, platelets or haemoglobin at which a transfusion of a particular blood component should be given. In 1989, a working party of the British Medical Association recognised that there was a need for further research into the indications for transfusion to develop “*professional consensus on the indications for prescribing blood and blood products based on scientific data and in particular, well conducted clinical trials rather than surgical and anaesthetic folklore.*”<sup>35</sup>

Also in 1989, guidance was published in Northern Ireland recommending that acute hospitals and health boards should establish committees in order to monitor and audit blood use. It recommended that the Northern Ireland Blood Transfusion Service should draw up regional guidance on the use of blood products.<sup>36</sup>

The bulk of the guidance governing best transfusion practice in the UK was produced in the 1990s onwards. The main publication was known as the “Red Book” and was first published in 1989.<sup>37</sup> It was drafted by members of the regional transfusion centres (“RTCs”) as well as the National Institute for Biological Standards and Control (“NIBSC”) and set the standards for best transfusion practice. There have been eight editions to date.

In 1991 the British Committee for Standards in Haematology produced guidelines for the use of fresh frozen plasma (“FFP”). This guidance noted that the number of units of FFP transfused in the last 15 years had increased more than tenfold.<sup>38</sup>

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32 Department of Health *Handbook of Transfusion Medicine* 1988 p3, p21, pp5-12 NHBT0099310\_002

33 British Society for Haematology *Guide Lines on Hospital Blood Bank Documentation and Procedures* 1984 NHBT0111389\_001, British Society for Haematology *Guidelines on hospital blood bank documentation and procedures* Clinical and Laboratory Haematology 1990 AHCH0000053

34 Guidelines were also produced by the British Society for Haematology addressing specific medical scenarios. For example: British Society for Haematology *Guidelines for transfusion for massive blood loss* Clinical and Laboratory Haematology 1988 NHBT0000037\_013

35 British Medical Association *Report of the Working Group on Transfusion Practice and HIV Infection in Scotland* 1989 p7 NHBT0010270\_003

36 Clinical Resource Efficiency Support Team *Blood: Use and Supply of Blood Products in Northern Ireland* 1989 pp2-3 SCGV0000004\_019. See below for further details about hospital transfusion committees.

37 Department of Health *Guidelines for the Blood Transfusion Services in the United Kingdom* 1989 NHBT0000027\_030

38 British Committee for Standards in Haematology *Guidelines for the use of fresh frozen plasma* Transfusion Medicine 1992 p1 BSHA0000021\_044

In the same year, a review, commissioned by the Department of Health, was undertaken about the practice of single-unit transfusions which noted that the practice of single-unit transfers “*incurs the risks of transmitting infection*” amongst other risks.<sup>39</sup> However, in certain rare circumstances single-unit transfusions were appropriate. Dr Jonathan Wallis, consultant haematologist at the Freeman Hospital in Newcastle from 1990 to 2019, told the Inquiry that the administration of single- and two-unit transfusions could be appropriate outside paediatrics in the case of very small adults, adults with an unstable cardiac state where volume overload is a concern, and where it is desired to raise haemoglobin by only 1g/dl. Some transfusion-dependent patients elected to have single-unit transfusions rather than multi-unit transfusions at longer intervals to maintain a steadier level of haemoglobin and better quality of life.<sup>40</sup>

In 1999, the British Committee for Standards in Haematology Blood Transfusion Task Force, in collaboration with the Royal College of Nursing and the Royal College of Surgeons of England, produced guidelines on the administration of blood and blood components which noted that as at 1999 there were “*no recognized guidelines on which to base local procedures for the ordering and administration of blood and the management of transfused patients*” and “*no single authoritative and comprehensive source supported by medical and nursing professional opinion.*”<sup>41</sup>

It was not until the 1990s that specific guidance was produced in relation to blood transfusions for infants. In 1994 the British Committee for Standards in Haematology published guidance which recognised that babies in special care units were “*amongst the most intensively transfused of all hospital patients.*” It described this area of transfusion practice as being “*beset with uncertainties*” and an area of medicine that would “*benefit from controlled investigation.*”<sup>42</sup> The 1994 guidelines were updated in 2004 to include older children.<sup>43</sup>

The publication of general guidance will not affect clinicians’ practice unless it is effectively shared with them through education and training, which is the next issue to consider. In addition to general guidance, speciality-specific guidance was also produced which is addressed below alongside the evidence relating to clinical practice in those areas.

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39 A “single unit” is not an alternative to “pooled units” in this context. Rather, the logic is that if all a patient “needs” is one unit, they should not usually be transfused: after all, donors giving blood usually give a unit at a time, and are expected to recover without difficulty from this loss of their blood. University of Sheffield Medical School Medical Care Research Unit *The Use of Single-Unit Blood Transfusion* November 1991 p3 DHSC0025270

40 Written Statement of Dr Jonathan Wallis para 90 WITN6982001

41 British Committee for Standards in Haematology et al *The administration of blood and blood components and the management of transfused patients* Transfusion Medicine 1999 p1 AHCH0000049

42 British Committee for Standards in Haematology *Guidelines for administration of blood products: transfusion of infants and neonates* Transfusion Medicine 1994 p1 BWCT0000093

43 British Committee for Standards in Haematology *Transfusion guidelines for neonates and older children* British Journal of Haematology 2004 BSHA0000042\_001

## Education, training and regulation

Education and training in transfusion medicine were provided by medical schools, with some input from the Royal Colleges and blood services.

The risk of transfusion-transmitted infections was taught to medical students from at least the 1970s. Dr Angela Robinson, when consultant in clinical haematology and blood transfusion to the Yorkshire RTC, used the maxim “*the safest transfusion is the one not given*” when giving lectures to undergraduates and postgraduates or when she was invited to give talks.<sup>44</sup> Dr George Galea, the director of Inverness and North of Scotland Blood Transfusion Service, recalls teaching medical students about the risks of transfusions and that “*the safest blood is the blood that’s not given.*” He told students not to “*go overboard*” with using blood.<sup>45</sup> Dr Vanessa Martlew described that throughout her career she always “*believed and taught that ‘blood is filthy stuff.’ We need to use it to save lives but it is not without risk and must be used appropriately*”, teaching these principles to “*undergraduate and postgraduate medical trainees and those engaged in professions allied to medicine for many years.*”<sup>46</sup>

However it is unclear how widespread this training was. A working party of the British Medical Association noted in 1989 that there was a need for more teaching time on transfusion in the medical undergraduate curriculum and in formal postgraduate courses. A recommendation was made for medical schools to give consideration to establishing academic departments, or at least academic posts, of transfusion medicine.<sup>47</sup>

Under the Medical Act 1983 the General Medical Council (“GMC”) had powers to oversee the basic medical education of doctors. However, this did not extend to setting or approving the content of undergraduate curricula, which was the responsibility of medical schools. The Royal Colleges – professional bodies responsible for the development and training of specific medical specialities – contributed to the development of the curricula for different medical specialities. There were no specific powers available to the GMC to approve or intervene

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44 Written Statement of Dr Angela Robinson paras 174-175 WITN6926001. Dr Robinson held this position 1976-88 and then became chief executive of the Yorkshire Regional Blood Transfusion Service 1988-94. CV of Dr Angela Robinson pp1-2 WITN6926002

45 Dr George Galea Transcript 3 December 2021 p25 INQY1000168. Dr Galea was a lecturer in haematology at Aberdeen University 1980-84, consultant in transfusion medicine to the Aberdeen and North East of Scotland Blood Transfusion Service 1989-93 and then regional transfusion director of the Inverness and North of Scotland and then the Dundee and East of Scotland blood transfusion services, 1993-96 and 1996-99, respectively. Written Statement of Dr George Galea para 2 WITN6931001. Dr Prentice, who was a consultant haematologist in Plymouth from 1981 described efforts to reduce the use of blood by surgeons wherever possible and to persuade colleagues to use saline instead of blood products for hypo-volaemic or shocked patients. Written Statement of Dr Archibald Prentice para 26 WITN5422001

46 Dr Martlew was consultant haematologist to the North West Regional Transfusion Service 1984-88, director of the Mersey and North Wales Regional Transfusion Service 1988-95 and consultant haematologist at the Royal Liverpool Hospital 1996-2020. Written Statement of Dr Vanessa Martlew para 5, para 303, para 1115 WITN4034001

47 British Medical Association *Report of the Working Group on Transfusion Practice and HIV Infection in Scotland* 1989 p7 NHBT0010270\_003



in postgraduate training until 2010, although the GMC made recommendations.<sup>48</sup> Until the 1990s the role of the GMC in regulating the actions of doctors in practice was limited.<sup>49</sup>

Once working in hospitals, in the main, clinicians were expected to learn on the job. Professor William Ribbans, an orthopaedic surgeon in practice since 1980, said that as a new employee at various hospitals he could not “*remember having any induction relating to Blood Transfusions. From 1980 to my last new job in 1996, I never received any formal induction education on any aspect of our work. Doctors simply turned up for work on their first day ... Nowadays, I am aware that all new doctors receive induction programmes on arrival at new hospitals.*”<sup>50</sup> Dr Jack Gillon, when working as a registrar and then lecturer in the gastrointestinal unit at the Western General Hospital in Edinburgh from 1977 to 1984, described in his oral evidence to the Inquiry that knowledge of transfusion medicine generally “*in the hospital setting in the 70s and early 80s was not good.*” In relation to the existence of guidelines about the use of transfusion, he said there was:

*“Virtually nothing. In those days, in the early 1980s, I don’t remember seeing any formal guidelines or protocols or anything, which was not unusual. This was very much at the beginning of the era of guidelines. They were a very new invention, they were not entirely popular, I don’t think, with many doctors, but very quickly, of course, as you know, that took off and became a very important part of our work.”*<sup>51</sup>

Dr Wallis described that in Newcastle:

*“Junior house officers (now known as F1) doctors joining the hospital had teaching on the mechanics of transfusion (how to arrange it, what to tell the patient etc) at induction, and a further session on the appropriate use of blood as part of their mandatory training during their period of stay. Copies of the Handbook for Transfusion medicine were widely circulated. At one stage in the early 2000s, copies were given to every junior doctor working at the hospital, though I cannot recall how long this continued. Subsequently an abbreviated guide to transfusion based on the ‘Indication codes for Transfusion’ document produced by the National Blood Transfusion Committee was distributed”*.<sup>52</sup>

During the 1970s and 1980s there was no mandatory requirement for clinicians to undertake continuing professional development.<sup>53</sup> The onus was on individual clinicians to keep themselves up to date with the latest medical knowledge: a “*reactive rather than proactive*

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48 Written Statement of Charles Massey para 4, para 9, para 12 WITN3365043

49 Written Statement of Charles Massey para 14 WITN3365001

50 Written Statement of Professor William Ribbans para 15(c) WITN7707001

51 Dr Jack Gillon Transcript 19 January 2022 pp7-8 INQY1000173

52 Written Statement of Dr Jonathan Wallis para 71 WITN6982001, National Blood Transfusion Committee *Indication Codes for Transfusion: An Audit Tool* September 2012 RLIT0000836

53 There was no statutory requirement for doctors to take part in continuing professional development (“CPD”) between 1980 and 2000. From 1993, the GMC’s position was that doctors should be “*aware of the importance of CPD.*” Written Statement of Charles Massey para 15 WITN3365043

*arrangement.*<sup>54</sup> Inevitably, clinicians tended to read material relevant to their own area of medicine.<sup>55</sup> Popular journals relevant to transfusion practice were *Transfusion*, *Vox Sanguinis* and *Transfusion Medicine*.<sup>56</sup> Dr Wallis told the Inquiry that all haematologists read the *British Journal of Haematology*, but only some haematologists would read *Transfusion Medicine*. Dr Wallis' impression was that regional colleagues “*in particular at the district hospitals in the region were pretty good on picking up on guidelines that were published.*”<sup>57</sup> However, other witnesses expressed concern about how effectively guidelines were cascaded and that published guidance had not “*percolated into the junior staff because there was no formal training programme.*”<sup>58</sup> Dr Dafydd Thomas, consultant in anaesthesia and intensive care at the Morriston Hospital, Wales from 1989, notes that there were no digital versions of national guidance initially “*so promoting their existence required great effort and attendance at various educational meetings.*” He was involved in the writing of British Committee for Standards in Haematology guidelines on platelets and has told the Inquiry that “*none of the clinicians I worked with had ever read them.*”<sup>59</sup>

In September 1974 Dr Peter Jones, director of the Newcastle Haemophilia Centre, along with Sister Maureen Fearn called for a government campaign “*to educate the medical profession in the recommended use of blood products, stressing the importance of using red cells rather than whole blood for most clinical problems*”. In order to ensure the effectiveness of any campaign, Dr Jones' view was that it should “*be directed at surgeons and junior hospital doctors.*”<sup>60</sup> No such government campaign was ever established. The central impetus behind this, however, was not that it was safer to give less blood where that was possible, but that using the red cell component of a donation would leave the plasma component available to increase domestic production of concentrates. Nonetheless, the essential message was the same: use less whole blood for transfusions. His call provided a further reason to do this.

National blood services provided some training to clinicians. Dr Jean Harrison, director and consultant haematologist of the North East Thames RTC from 1981 to 1995, has told the Inquiry that the RTC provided teaching and training for senior registrars in haematology in blood transfusion. This was a one-week revision course that took place prior to exams. She describes it as “*compulsory*” for senior registrars in haematology to undergo training by the blood service as part of their training for the Member of the Royal College of Pathologists (“MRCPath”) qualification. Laboratory and nursing staff also attended training courses.<sup>61</sup>

Dr Robinson emphasised that:

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54 Professor Philip Steer Transcript 23 February 2022 p79 INQY1000186

55 Dr Jonathan Wallis Transcript 24 February 2022 p8 INQY1000187

56 Written Statement of Dr Jack Gillon para 16 WITN6987001

57 Dr Jonathan Wallis Transcript 24 February 2022 pp8-9 INQY1000187

58 Professor Philip Steer Transcript 23 February 2022 p79 INQY1000186

59 Written Statement of Dr Dafydd Thomas para 109, para 118 WITN6973001

60 Jones and Fearn *Optimum Use of Factor VIII Preparations at Present Available in the United Kingdom* September 1974 p3 OXUH0000757

61 Written Statement of Dr Jean Harrison para 23, para 401 WITN7046001



*“the blood service has always recognised that it has a role, which increased over the years, in advising and educating clinicians as to the risks of blood and blood products and as to appropriate use of blood and good transfusion practice. Dating back to the discovery of the likely transmission of jaundice in the Second World War its message has always been that blood or blood components should only be used when strictly necessary and in the absence of alternatives.”*<sup>62</sup>

This is a role that continues today: NHSBT is involved in writing the transfusion guidelines for the British Society for Haematology and the National Institute for Health and Care Excellence (“NICE”) guidelines, as well as examining doctors for the Fellowship of the Royal College of Pathologists (“FRCPath”) qualification.<sup>63</sup>

From the 1990s onwards, the training programme for junior doctors (those who are not yet consultants) has become more formalised. Following the Calman report in 1993, structured, higher specialist training was introduced. A specialist registrar grade was created.<sup>64</sup> For the first time, there was mandatory training of a maximum of seven years and all doctors had to be on the GMC register of specialists before being able to take up a substantive consultant post. In 2002, a report by Sir Liam Donaldson described the unstructured training for senior house officers, and partly to address this the “Modernising Medical Careers” programme was established in 2005.<sup>65</sup> Doctors were required to undergo a two-year foundation programme after graduation and then to undertake speciality training. The Specialist Training Authority was established in 1995, followed by the Postgraduate Medical Education and Training Board in 2005, which merged with the GMC in 2010.<sup>66</sup>

All clinicians, both junior doctors and consultants, are now required to keep up to date with medical developments via continuous professional development. Medical staff are required by the GMC to undergo annual appraisal which is linked to revalidation.<sup>67</sup>

However, despite the changes in medical training, some witnesses have expressed concerns about whether a proper mechanism exists for junior doctors to be made aware of new guidelines. For example, Professor Philip Steer described that in the last three to four years, he would ask trainees about a specific guideline and trainees would not have read it. He said that junior doctors in the North West Thames Region arranged their own training, for an afternoon a month, because they were not being provided with sufficient training.

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- 62 Written Statement of Dr Angela Robinson para 24 WITN6926003. After her work in Yorkshire, Dr Robinson became medical director of the National Blood Authority and then of NHSBT 1994-2007. Written Statement of Dr Angela Robinson p3 WITN6926003
- 63 Written Statement of Dr Gail Mifflin para 244 WITN0672006. Dr Gail Mifflin was appointed as NHSBT’s chief medical officer and director of clinical services in 2016.
- 64 This later led to the speciality registrar post.
- 65 Patel *Changes to postgraduate medical education in the 21st century* Clinical Medicine 2016 p1 RLIT0002216
- 66 Written Statement of Charles Massey para 11 WITN3365043
- 67 Written Statement of Professor Colin Melville para 5.4 WITN7248001, Professor Colin Melville Transcript 15 November 2022 pp115-124 INQY1000262

Another concern that has been raised is whether clinicians have time to read the newly published national guidance in light of the pressures on workloads.<sup>68</sup>

The next section of this chapter gives an overview of the attitude of clinicians to blood transfusion and experiences of patients before considering the practices adopted in respect of the administration of blood in specific medical disciplines.

## Attitudes of clinicians towards blood transfusion

On the ground, it appears that, despite the training received and the content of medical textbooks, in the 1970s and 1980s many UK clinicians viewed blood as safe and effective. Professor Mollison's *Blood Transfusion in Clinical Medicine* described that "a generation of medical men" grew up believing that blood transfusion was "one of the simplest forms of therapy" as a result of the use of blood during the Second World War where group O blood was given "as a general panacea for the injuries of war".<sup>69</sup> Professor John Fairclough, a consultant orthopaedic surgeon who practised in Wales from 1981, described that "*Blood to a surgeon was like a medication in that you were aware of need but assumed its safety.*"<sup>70</sup>

On the whole – and with notable exceptions – there was generally a liberal approach in practice to the use of blood. This was especially the case in certain medical disciplines.

Some clinicians were particularly aware of the dangers of viral infections arising from blood due to cases of doctors being infected with Hepatitis B during the course of their employment. One example was the death of a junior doctor at King's College Hospital in the 1980s, who sustained a needlestick injury, developed acute Hepatitis B and died from liver failure. This brought home to doctors who knew the junior doctor, the seriousness of the risks.<sup>71</sup> Dr Archibald Prentice speaking of the early 1980s said: "*I was concerned that surgeons were wasting blood by having too much cross-matched for any particular operation. Over a six month period I was able to demonstrate that for a particular operation the average amount of blood product used was a certain level, much lower than generally requested by the surgeons and we agreed that it was sensible to cross-match at a reduced level. It reduced usage of blood and blood products in operations by around 25%.*"<sup>72</sup> For other clinicians, a conservative approach to the administration of blood arose from an academic interest in best transfusion practice and concerns over patient safety.<sup>73</sup> Still others were concerned about limitations in supply and expense of blood: Dr David Bogod, a consultant anaesthetist who qualified in 1980 told the Inquiry: "*In general, throughout my career, it*

68 Professor Philip Steer Transcript 23 February 2022 p61, p81 INQY1000186. Professor Steer was consultant in obstetrics and gynaecology to the West London and Charing Cross and Westminster Hospitals 1989-2004 and to the Chelsea and Westminster Hospital 1994-2014 and editor-in-chief of the *BJOG – an International Journal of Obstetrics and Gynaecology* 2005-2012.

69 Mollison *Blood Transfusion in Clinical Medicine* 1951 p10 RLIT0001567

70 Written Statement of Professor John Fairclough para 55 WITN7705001

71 Written Statement of Professor Philip Steer pp30-31 WITN6977001

72 Written Statement of Dr Archibald Prentice para 26 WITN5422001

73 Written Statement of Professor Philip Steer p5 WITN6977001

*would be fair to say that transfusion was regarded as a rarely-used but valuable resource, to be employed sparingly because of relative scarcity of supply and expense of provision.”<sup>74</sup>*

With the advent of AIDS, questions about blood transfusion practice and the giving of blood started to be asked. This led to a change in attitude about the safety of blood. Dr Roger Moore, the deputy national director of the NBTs from 1989 to 1992, describes that: *“Originally the benefits of a blood transfusion had been seen as overwhelming compared with the risk. A patient either had a certainty of dying at once of blood loss or a vague possibility of an infection years into the future. The advent of AIDS changed perceptions, patients and their doctors were very concerned about getting AIDS from a transfusion, the risk/benefit equation changed.”<sup>75</sup>*

The preface to Dr Tony Napier’s 1987 book on blood transfusion noted that *“The recent and quite unexpected appearance of AIDS ... must serve to displace any feelings of complacency about the safety of transfusion that may have arisen”*.<sup>76</sup>

Clinicians’ awareness of the need only to use blood when necessary appears to have grown throughout the 1990s. This resulted in new initiatives to ensure the better use of blood. These are addressed after considering the attitudes of clinicians in individual medical disciplines.

## Individual medical disciplines

The general picture just described covers a number of medical specialties, some of which used blood more liberally than others during the 1970s and 1980s. In particular, obstetrics and gynaecology, and surgery and orthopaedics had a reputation in some UK hospitals for being enthusiastic about giving blood. From the broad range of statements that the Inquiry has received, those two stand out for more detailed consideration, as well as anaesthesia and the treatment of inherited blood disorders such as thalassaemia, sickle cell disease, and some leukaemias.

Again, it cannot be assumed that what is true in general holds true in each individual case – indeed, whilst general trends in blood usage as between medical disciplines can be identified, there was also significant variation between different clinicians within the same discipline.

Dr Wallis highlighted that the time when the clinician first developed a practice which became routine for them was an important factor in whether or not unnecessary use of blood was a feature of their clinical practice:

*“A lot of it was probably person specific. If we take, say, orthopaedics, some of the younger surgeons were very good at avoiding use of blood, whereas some of the older ones were in the habit of transfusing fairly freely. So I think there was a lot of*

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74 Written Statement of Dr David Bogod p7 WITN6975001

75 Written Statement of Dr Roger Moore para 133.3 WITN6919001

76 Napier *Blood Transfusion Therapy: A Problem-Orientated Approach* 1987 p8 RLIT0001565. Dr Napier was the medical director of the Welsh Regional Blood Transfusion Service 1977-98. Written Statement of Dr John Napier para 9 WITN6915001

*individual variation between people within a single department. In cardiothoracic surgery, I think there was a general understanding that they preferred not to use so much blood. We used to feed back figures to them on a regular basis, and surgeons are competitive animals and would take -- if they had excessive blood use compared to a colleague, would be worried about that. That was probably one of the most effective things you could do if you wanted to reduce blood use. So I think more variation between persons than between departments.”<sup>77</sup>*

Other sources however suggest that junior staff were more likely to order blood than their senior counterparts.<sup>78</sup> For example, a study published in 1983 about the blood use of consultant surgeons, anaesthetists and house surgeons at five hospitals in Wessex found “*substantial and unintentional over-ordering*” of blood by junior staff because, according to authors of another study, junior staff who had not “*received any formal instructions, were much more likely than senior staff to over-order blood.*”<sup>79</sup>

### **Obstetrics and gynaecology**

The two primary scenarios in which blood was given to pregnant and postpartum women from the 1950s to the 1990s were where there was acute blood loss or anaemia.

Acute blood loss generally arose from delivery or was due to haemorrhage before, during or after delivery. A postpartum haemorrhage occurs where the placental bed bleeds extensively if the placenta does not detach correctly during childbirth.<sup>80</sup> In cases of acute massive blood loss, the amount of blood required is normally determined by the volume of blood lost. Such blood loss can be rapid: patients who refuse transfusion in the context of haemorrhage have a six-times increased risk of maternal death.<sup>81</sup> In the circumstances of high-volume, acute blood loss, it is clear that blood transfusions were and are necessary. However, the Inquiry has received statements from women who did not receive any or any adequate information about the need for a blood transfusion in circumstances of massive blood loss. For example, one woman who lost a lot of blood following a forceps delivery of her twins in 1989 has told the Inquiry that “*I was not seen by a doctor. I do not remember having any information about being treated for anaemia and I was not asked to decide on the treatment or given a choice. I was not informed of any risks. The only consultation I had, was the nurse telling me that I would ‘Feel like a new woman in the morning’ as she hung up the blood on the drip.*”<sup>82</sup>

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77 Dr Jonathan Wallis Transcript 24 February 2022 pp39-40 INQY1000187

78 There is, of course, a distinction between overordering and overuse.

79 Smallwood *Use of blood in elective general surgery: an area of wasted resources* British Medical Journal 1983 p1 RLIT0001007, Pathi et al *It’s Scotland’s blood, so why waste it?* Journal of the Royal College of Surgeons of Edinburgh 1987 p1 RLIT0001020

80 Written Statement of Professor Philip Steer p30, p5 WITN6977001

81 Written Statement of Dr David Bogod p13, p23 WITN6975001

82 Written Statement of ANON para 6 WITN0277001

The woman was infected with Hepatitis C and was awarded compensation by the High Court in 2001.<sup>83</sup>

The threshold of when to transfuse in the context of postpartum haemorrhage has changed over time. In 1982 the leading anaesthesia textbook cited 10g/dl as the requisite haemoglobin level for a transfusion in a healthy patient. By 2007 this had shifted to 8g/dl and by 2019 to 7g/dl.<sup>84</sup> In terms of volume of blood loss (which is notoriously difficult to measure with any accuracy), the threshold for transfusion due to such a haemorrhage was previously 500ml of blood loss but is now usually 1,000ml. In the early 2000s NICE started to produce maternity guidelines.<sup>85</sup> The April 2004 guideline on caesarean section refers to transfusion only where there is an increased risk of blood loss greater than 1,000ml.<sup>86</sup> No further guidance on transfusion is given.

Where there was modest or minor blood loss, from the 1970s transfusions were commonly given to women after labour to help get a woman “*up and about*” and caring for their baby, giving them a “*top up*” of one or two units of blood after labour because they were thought to be anaemic.<sup>87</sup> Many women who received postpartum blood transfusions have described this as the reason they were given for having a transfusion. For example, Deborah Jones was given a blood transfusion at St David’s Hospital in Bangor, North Wales, in 1980 after a normal delivery. She was told by a nurse on the ward that she “*would be given a blood transfusion the following morning ... She told me that I was a bit anaemic and would be bouncing about down the ward after the transfusion.*”<sup>88</sup> Michele Claire, who was given two blood transfusions after the birth of her children in 1985 and 1988, recalls that after the birth of her daughter in 1985 “*whilst in recovery, a junior doctor, who I had never seen before and who I did not see again, told me that he was going to give me a blood transfusion, in his words ‘you look a little peaky my dear’. I was supposedly given this transfusion as my iron count was low, however my medical records show that I have had a low iron count since childhood.*” She describes herself as feeling “*bullied into accepting the transfusion*” as her husband “*took the side of the junior doctor, as he implicitly trusted the medical profession.*”<sup>89</sup>

Some women were not even told that they would receive a transfusion. Susan Dennison was 21 when she received a blood transfusion in 1981 at the Peterborough Hospital. “*The doctor did not say the word ‘transfusion’, just that I needed some blood. I did not know that I had received a transfusion at the time, let alone what the risks of receiving one might be. I simply followed the doctor’s advice as I assumed that he knew what I needed in order to be able to take good care of my daughter.*” As it was the birth of her first child: “*I did not know what to expect. My doctor simply told me that I would be getting a bit of blood to help me*

83 She was a lead claimant in the *A and Others v National Blood Authority* litigation. Written Statement of ANON para 2 WITN0277001

84 Written Statement of Dr David Bogod p10 WITN6975001

85 Written Statement of Professor Philip Steer p5 WITN6977001

86 NICE *Clinical Guideline 13 Caesarean section* April 2004 p15 RLIT0000954

87 Written Statement of Professor Philip Steer p16 WITN6977001

88 Written Statement of Deborah Jones para 3 WITN1913001

89 Written Statement of Michele Claire paras 3-7 WITN0108001



recover. I asked the doctor what the blood was for, and he told me that it was to prevent me from feeling tired and becoming anaemic, as I had haemorrhaged quite a bit during the birth. He said that if I became anaemic I would need to stay in hospital longer and would have trouble looking after my baby.” At the six-week postnatal check-up her GP queried whether a blood transfusion had been required. She did not find out that she was infected with Hepatitis C until 2014.<sup>90</sup>

Professor Mollison’s textbook in the 1983 edition described the practice of “topping up” post-operatively as “widespread” but with “very variable opinions as to what constitutes an acceptable level” of haemoglobin.<sup>91</sup> This practice does not appear to have been unique to the UK and was also apparent internationally, for example in obstetrics in Sweden and in the US.<sup>92</sup>

Research in the 1960s demonstrated that pregnant women have a lower average haemoglobin concentration than their non-pregnant counterparts. In 1962 Dr David Paintin produced research that demonstrated that during pregnancy, plasma volume expands faster than red cell volume. Hence the concentration of red cells falls.<sup>93</sup> Professor Steer, who had been mentored by Dr Paintin, told the Inquiry that the average fall in pregnancy of haemoglobin is about 10g/litre and in some healthy women, who have a high haemoglobin concentration to start with, it can be as much as 30g/litre.<sup>94</sup> He therefore took a “conservative approach” to giving blood transfusion to pregnant or postpartum women. His practice was to use blood transfusion to address “the effects of acute blood loss” rather than cases of anaemia. He described the existence of an “excessive willingness” to diagnose anaemia and that “clinical colleagues were too ready” to give haematinics and blood transfusions.<sup>95</sup>

Nevertheless, the practice of giving one or two units of blood remained so as “to be on the safe side” in case a woman were to bleed postnatally, as well as benefiting the clinician in ensuring they did not have to return to the ward because the patient had deteriorated.<sup>96</sup> This practice extended to the use of two units where one would suffice and this appears to have been both widespread and persistent: a 2017 study of two large maternity units in Texas and London found that from 1988 to 2000 obstetricians more commonly prescribed two units rather than one unit “even when the [estimated blood loss] and pre-transfusion haemoglobin suggest that one unit would be sufficient”. There was an almost sixfold preference for two units compared to one unit. Such a practice “continues to deviate from

90 Written Statement of Susan Dennison paras 4-8 WITN2009001

91 Mollison *Blood Transfusion in Clinical Medicine* 1983 p72 RLIT0001571

92 Professor Philip Steer Transcript 23 February 2022 p32 INQY1000186

93 Paintin *The size of the total red cell volume in pregnancy* Journal of Obstetrics and Gynaecology 1962 WITN6977003. See also Steer et al *Relation between maternal haemoglobin concentration and birth weight in different ethnic groups* British Medical Journal 25 February 1995 WITN6977005

94 Professor Philip Steer Transcript 23 February 2022 pp13-14 INQY1000186. 10g/litre = 1g/dl; 30g/litre = 3g/dl.

95 Haematinics increase the amount of haemoglobin in blood, such as iron. Written Statement of Professor Philip Steer p13, pp5-6 WITN6977001

96 Professor Philip Steer Transcript 23 February 2022 p32 INQY1000186. Those taking a conservative approach have noted that the solution to further bleeding was to order, but not administer, further units so it was on standby.

*recommended guidelines*".<sup>97</sup> Professor Steer recalls a discussion with colleagues in 2016 after he presented data about the number of women receiving two units. He was surprised at "a number of colleagues who said, 'Ah, well, no, we think it is a good idea. You know, if you have two units cross-matched, you might as well give it, give the woman a boost and she will feel better and her recovery will be speeded up', despite the fact we had already presented the evidence from our academic point of view this was not justified."<sup>98</sup> It is concerning that the practice of giving two units rather than one is not an historic issue.

Not only were there viable alternatives to blood transfusion for women who were anaemic post-birth, particularly by prescribing iron, but research suggested that the practice of giving two units was probably not effective. The "benefit" of administering two units of blood postpartum for anaemia probably only lasted for around 48 to 72 hours and published literature suggested a benefit of a week to 10 days at the maximum.<sup>99</sup>

It is clear that some patients received blood that they did not need and were infected with hepatitis or HIV in consequence. Angela Irons received a blood transfusion of two units in 1985 the day after she had her son at Dryburn Hospital in Durham. She had a haemoglobin level of 9.1 prior to the transfusion, and does not think she was actively bleeding. She was diagnosed with Hepatitis C in 2000.<sup>100</sup> There are many other examples amongst the statements received by the Inquiry.

The practice of giving two units extended to gynaecological procedures. Dr Discombe in 1960 described the "very common" practice in gynaecological cases, particularly in cases of fibroids, of pre-operative transfusion to raise the haemoglobin. In his opinion "every woman placed on a surgical waiting list should be treated with small doses of iron" as an alternative.<sup>101</sup> Once again it is clear that some patients were transfused unnecessarily. Maureen Drane underwent a hysterectomy in 1994 and was transfused with two units of blood. Her widower has told the Inquiry that following the surgery he and his wife were told by clinicians that she had received a blood transfusion and that she "could have possibly managed without having the blood transfusion, but would have taken a little longer to recover." She died in 2018 with the cause of death recorded as "upper gastrointestinal bleeding of unknown origin and liver cirrhosis secondary to hepatitis C."<sup>102</sup>

## Surgery and orthopaedics

Most blood transfusions initiated or managed by anaesthetists take place in the context of surgical procedures, during or immediately after surgery, and arise due to massive blood

97 Cauldwell et al *Retrospective surveys of obstetric red cell transfusion practice in the UK and USA* International Journal of Gynecology & Obstetrics 13 September 2017 p3 RCOG0000025

98 Professor Philip Steer Transcript 23 February 2022 pp30-31 INQY1000186

99 Professor Philip Steer Transcript 23 February 2022 pp25-26 INQY1000186. See below for further consideration of prescribing iron.

100 Written Statement of Angela Irons paras 2-11 WITN1910001

101 Discombe *Blood Transfusion: A Guide to the Practice of Transfusion within Hospitals* 1960 p22 RCSE0000002

102 Written Statement of Terence Drane para 21, para 27 WITN3286001



loss. Therefore, the consideration of transfusion-transmitted infections was generally viewed as a small risk in the circumstances: *“As anaesthetists, the risk-benefit balance of acute transfusion was nearly always hugely weighted toward benefit, often being a life-saving intervention, so the small risk of infection posed no significant barrier to our use of blood or blood products.”*<sup>103</sup>

However, “topping up” blood with two units was also customary for some general and orthopaedic surgeons.<sup>104</sup>

Dr Moore recalled from his time in the DHSS: *“in some surgical practice, even when blood loss during surgery had been minor, it was customary to give a ‘top up’ of a unit or two to aid recovery. I have witnessed this myself in orthopaedic surgery in the early 1980s. The risk/benefit balance in those circumstances is much less clear cut.”*<sup>105</sup> Another clinician described the approach of orthopaedic surgeons in Morrision Hospital, Wales of always transfusing two to three units when performing total knee replacements.<sup>106</sup>

Such an approach was inconsistent with the published guidance on blood transfusion in surgery. The 1984 *Textbook on Surgery* highlighted that *“blood transfusion carries some risk and alternative methods should be chosen whenever possible. Anaemia is often better corrected before operation by prescribing oral or parenteral iron.”*<sup>107</sup> In the 1985 *Principles and Practice of Surgery*, authored by three surgeons at Scottish hospitals, the transmission of viral hepatitis was described as *“the most serious and frequent complication of the administration of blood and blood products ... The best preventative measure is to avoid unnecessary transfusion.”* It noted that the use of haemoglobin and haematocrit measures was *“notoriously misleading”* and the best approach to assessing haemorrhage was for frequent clinical observations such as increasing pulse rate, falling blood pressure, irritability, sweating, cold extremities, intolerance to exertion and frequent changing of posture.<sup>108</sup>

Many clinicians with a specialist interest in blood transfusion have told the Inquiry that it has been difficult to get the message out that “topping up” is not medically necessary. For example, in his oral evidence to the Inquiry Professor Mark Bellamy explained the following in the context of red cells:

*“there’s pretty good evidence that apart from in certain patient groups, like cardiac surgery ... it’s better not to transfuse to ‘normal’ blood count values but to adopt a lower target, a restrictive transfusion threshold. So if a normal blood count was, say, 113 grams per litre, then you shouldn’t be transfusing to 113 grams per litre, because people do just as well if you keep them in the 70-90 bracket, without having the complications of that additional blood transfusion. Getting*

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103 Written Statement of Dr David Bogod p31, p26 WITN6975001

104 For example see: Written Statement of Professor William Ribbans p18 WITN7707001

105 Written Statement of Dr Roger Moore para 133.5 WITN6919001

106 Written Statement of Dr Dafydd Thomas para 61 WITN6973001

107 Macfarlane and Thomas *Textbook on Surgery* 1984 p2 NHBT0000114\_042

108 Forrest, Carter and Macleod *Principles and Practice of Surgery* 1985 p8, p11 NHBT0000114\_105

*that message out to other teams around the hospital, other clinicians outside of critical care, can be very difficult. So you'll have -- Dr X will wander in to see his patient who has been admitted to critical care and sneakily prescribe two units of blood to bring them back up to 113, completely unnecessarily, but he thinks he's doing the right thing because he's correcting the numbers, not based necessarily on evidence.”<sup>109</sup>*

Professor Ribbans told the Inquiry that over the course of his career as a consultant orthopaedic surgeon in England, from 1980 to 2012, *“less and less patients were transfused peri- and post-operatively. This was led predominantly by anaesthetists and the realisation that most patients can tolerate lower Hb [haemoglobin] levels without untoward side-effects than believed in the past.”* He stated that the threshold for giving blood changed during his career: *“towards the end of my surgical career, in a haemodynamically stable patient, a transfusion threshold of 7-8g/dL would be reasonable. 40 years previously that threshold was more likely to be 9-10g/dL.”<sup>110</sup>*

The Inquiry has received a number of statements where individuals had elective surgery and state that they were not informed of the risks of blood transfusions. For example, Ann Foster had what should have been a routine gallbladder operation in around 1990-92, was told she had contracted Hepatitis C, and died in 2016 after a long period of decline. Her son reports that she was not told of any of the risks of the transfusions she was to have; when following her surgery she became obviously jaundiced, no explanation was given to her as to **how** she had contracted Hepatitis C; and it was only as she lay dying some 26 years later that a consultant said that the blood transfusion had been the source.<sup>111</sup>

In December 1985 a woman in her late forties had a hysterectomy. She remembers that she was anaemic before her surgery. She was not told of any risks of infection from the transfusions she then had. In 1993 she developed what seemed to be flu, and was told a virus was present in her blood (but it remained unidentified), and later was told she had myalgic encephalomyelitis (“ME”). She had little energy, dizziness, brain fog, flu-like aches and pains, discomfort in bright light and tinnitus, leading to anxiety and depression. It was not until 2009 that her infection with Hepatitis C was identified.<sup>112</sup>

## **Fresh warm blood**

Dr Colin Hilton, a cardiothoracic surgeon who worked in Newcastle from 1979 to 2005, has told the Inquiry that on one occasion at the Freeman Hospital he used fresh warm blood *“when other available means to stem the bleeding had been exhausted.”* He described the use of fresh warm blood as a *“last resort as a life saving measure.”* As a trainee at

109 Professor Mark Bellamy Transcript 16 November 2022 pp160-161 INQY1000263. Professor Bellamy has chaired the SHOT Steering Group since 2017. Written Statement of Professor Mark Bellamy para 2 WITN7312001

110 Written Statement of Professor William Ribbans p8, p17 WITN7707001

111 Written Statement of Mark Foster paras 4-6 WITN3965001

112 Written Statement of ANON paras 3-13 WITN5943001

the Harefield Hospital in Middlesex in 1973-76 he had seen fresh warm blood taken from donors at the Royal Air Forces, Uxbridge. He stated that he has “*no knowledge of the screening procedures undertaken.*” He described the use of fresh warm blood as “*rare*”. He did not repeat it following warnings from his colleagues. He states that such use was in retrospect “*unwise*”.<sup>113</sup>

The particular danger of using fresh warm blood was that it was untested: the screening practices of the NBTS would not have been applied; it would not have been screened for Hepatitis B nor, after October 1985, for HIV, nor for syphilis and there would be most unlikely to have been a record of the donation, or the amount given, which might enable an infectious donation to be traced back. In a letter of 3 February 1988 Dr (later Professor Dame) Marcela Contreras said that she was “*aware of at least 2 cases of transfusion-transmitted AIDS in this country where the recipient received untested, non-NBTS, fresh, warm blood. The transfusion records for such patients are appalling, and it will be impossible to find the ‘culprit’ donor, since the source and the amount given are both unrecorded.*”<sup>114</sup> In short, the practice was (usually) reckless.

In around the mid 1980s Professor Sir Magdi Yacoub, of the Harefield Hospital and the Royal Brompton Hospital in London, was a proponent of fresh warm blood. Professor Dame Marcela Contreras describes him as performing “*pioneering heart and heart – lung transplantation surgery as well as lifesaving cardiac surgery on very sick new-born infants.*” He used fresh warm blood due to the clinical benefits he believed it provided.<sup>115</sup>

Dr Contreras discussed her concern and disapproval of his practice with Professor Yacoub “*on numerous occasions*” but understood that he continued “*bleeding members of staff, visiting doctors and members of the Armed Forces for his numerous ‘emergencies’.*”<sup>116</sup> The DHSS took the view that the use of untested blood was “*highly undesirable*”; unnecessary because “*testing can be done in a matter of minutes*” and that there could be “*no excuse for not labelling blood ... properly and for not keeping adequate records*” but that the practice of using fresh warm blood was more controversial, and a number of clinicians like Professor Yacoub were firmly convinced of its efficacy.<sup>117</sup> Dr Contreras had initially reluctantly facilitated the process by providing same day whole blood because the alternatives were of greater risk – because if provided by the blood service the blood, albeit untested, would be collected

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113 Written Statement of Dr Colin Hilton paras 18-25 WITN6913001

114 Letter from Dr Contreras to Dr John Burman 3 February 1988 p2 NHBT0085681\_039. The Inquiry has no further knowledge of these two cases, but there is no reason to think that Dr Contreras had been misinformed. It evidences at least two cases in which, on the limited material available, it appears two patients were given AIDS because of a recklessly unsafe practice adopted at their hospitals.

115 Written Statement of Professor Dame Marcela Contreras para 484, para 502 WITN5711001

116 Letter from Dr Contreras to Malcolm Harris 19 July 1988 DHSC0002841\_009. Dr Contreras had already raised the problem with the consultant haematologist Dr Burman at the National Heart and Chest Hospital where Professor Yacoub practised, written to Professor Yacoub to complain of his practices, and had sought advice on her legal position if she complied with Professor Yacoub’s requests, on which the Medical Defence Union supported her approach. Letter from Dr Contreras to Dr Burman 3 February 1988 NHBT0085681\_039, Letter from Dr Contreras to Professor Yacoub 4 May 1988 DHSC0002841\_012, Letter from Dr Contreras to the Medical Defence Union 19 May 1988 NHBT0093056, Letter from the Medical Defence Union to Dr Contreras 2 June 1988 NHBT0101369

117 Internal DHSS memo from Dr Peter Doyle 28 July 1988 DHSC0002841\_007

from known or repeat donors, whereas the alternative would be that Professor Yacoub would obtain it from other sources “*which would inevitably carry more risks.*”<sup>118</sup>

A meeting was held on 17 October 1988 to discuss his use of fresh blood.<sup>119</sup> The arrangements for the North London Blood Transfusion Centre to provide blood stopped. This was principally as a result of the introduction of the Consumer Protection Act 1987.<sup>120</sup> However, the practice of Professor Yacoub using fresh warm blood continued. His doing so still remained an issue in 1999<sup>121</sup> and inferentially until he retired in 2001.<sup>122</sup> He told the Inquiry that he used fresh warm blood only when the situation was one of extreme emergency, in order to prevent imminent death.<sup>123</sup> He did so in less than 1% of cases.<sup>124</sup> He says “*I am not aware that any of these patients were infected by the use of fresh warm blood.*”<sup>125</sup>

### Failure to inform about transfusions

Dr Lorna Williamson has told the Inquiry that the Hepatitis C lookback revealed that “*some patients who had planned surgery did not know whether or not they had been transfused while under anaesthetic.*”<sup>126</sup>

The Inquiry has received many statements where individuals state that they were not informed of the risks of blood transfusions, and others where they were not even told that they had received blood and for many it was not recorded in the medical records that were retained after their hospital stay. One man, who was infected with Hepatitis C, was injured while working on an offshore rig in 1974. He suffered a broken hip, pelvis and left arm as well as pelvic abrasions and cuts. He was given the blood transfusion when unconscious:

*“Throughout the duration of my time at both hospitals I was not informed that I had been given a blood transfusion, and neither was my consent sought for one. The doctors who treated me provided me with little to no information about what had happened to me after the accident, the extent of my injuries, and most*

118 Written Statement of Professor Dame Marcela Contreras para 488, para 491, para 493 WITN5711001

119 From a letter written by Dr Contreras after the meeting, asking for some corrections to the minutes, it appears there was still an impasse as to what was being done. Letter from Dr Contreras to the Hillingdon Health Authority District General Manager 25 October 1988 NHBT0101365

120 Written Statement of Professor Dame Marcela Contreras paras 508-509 WITN5711001

121 Email from Dr Contreras to Peter Garwood and others 18 March 1999 NHBT0101360

122 Written Statement of Professor Sir Magdi Yacoub para 17 WITN4129001

123 Professor Dame Marcela Contreras confirms that she saw from observation of what she described as a miracle for some small babies who received fresh warm blood, that it might indeed have some intra-operative advantages, though she did not express a concluded view. Professor Dame Marcela Contreras Transcript 3 December 2021 pp122-133 INQY1000166

124 He gives the figure as “*approximately 0.7%*”. He accepts he did not discuss the possibility of its use with a patient beforehand, given that use during a cardiac procedure was a rare occurrence. Written Statement of Professor Sir Magdi Yacoub paras 16-17 WITN4129001

125 Written Statement of Professor Sir Magdi Yacoub para 25 WITN4129001. The Inquiry has no evidence either to confirm or to contradict the absence of infections.

126 Written Statement of Dr Lorna Williamson para 777 WITN0643010. Dr Williamson was medical and research director of NHSBT 2007-2016.

*importantly the blood transfusion. It was only years later, in 2003 ... that I found out that I had received a blood transfusion. I received 8 or 10 units of blood”.*

He found out when his GP looked through his medical records.<sup>127</sup>

## Inherited blood disorders

Patients born with inherited blood disorders require frequent blood transfusions. The two most common are beta thalassaemia and sickle cell anaemia.

Beta thalassaemia is a genetic disorder of haemoglobin production. The disorder is due to a range of mutations in the beta globin gene. There is a continuum of clinical severity, with transfusion-dependent thalassaemia and non-transfusion-dependent thalassaemia. For patients with transfusion-dependent thalassaemia, red blood cell transfusions are required every two to four weeks. Emma Prescott, thalassaemia nurse specialist at the Whittington Hospital from 1995 to the present, explained that *“death at an early age is inevitable if no transfusions are given.”*<sup>128</sup>

Some individuals with beta thalassaemia have told the Inquiry that they were not aware of the link between blood transfusions and transfusion-transmitted infections. For example, Maria Fletcher, who has beta thalassaemia major and was infected with Hepatitis C, states:

*“I was never given any information or advice about the possibility or risk of being exposed to infection before receiving any blood; ... I believe that I (or my parents) should have been informed about the risks associated with having a blood transfusion before I was treated. My parents and I could have been alert to any possible side effects and sought help sooner.”*<sup>129</sup>

Terri Kuman also describes a similar position with her husband, Cem, who was infected with Hepatitis C from blood transfusions he received to manage his beta thalassaemia major:

*“Cem – and Cem’s parents while he was a child – consented to him being given blood transfusions as he understood them to be lifesaving treatment for his thalassaemia. However, Cem was not fully informed of the link between transfusions and blood borne diseases. He believed the transfusions were totally safe and necessary. The only risk he was ever made aware of was the reaction he could have if the blood was transfused too quickly.”*<sup>130</sup>

Sickle cell disease is a family of inherited anaemias. The sickle cell gene gives rise to sickle haemoglobin as a result of a mutation in the gene changing the beta globin chain of haemoglobin. The distorted sickle cell shaped cells affect the delivery of oxygen to tissues,

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127 Written Statement of ANON paras 2-6 WITN2097001

128 Written Statement of Emma Prescott para 5.2, para 5.6 WITN6979001

129 Written Statement of Maria Fletcher para 9, para 14 WITN1876001

130 Written Statement of Terri Kuman para 13 WITN3326001



which can cause significant pain and in severe cases, death.<sup>131</sup> Exchange transfusions may be required which involve the giving of red cell concentrates. Professor Dame Sally Davies, who was appointed as consultant haematologist at Central Middlesex Hospital in 1985 with a specific remit for sickle cell disease, describes that sickle cell patients were rarely treated with “*simple additive red-cell transfusions*” due to risks of raising blood viscosity and causing stroke. Adult patients undergoing exchange transfusion (removing their blood and replacing it with transfused blood) generally received 8 to 12 units of red cell concentrates over three to four days. She described that severely affected patients were aware of the risks of blood transfusion – including the risk of transfusion-related infection – because there was “*frequent discussion within the community of the risks of transfusion.*” She stated that “*blood transfusion in sickle cell patients was never undertaken lightly but it also saved many lives.*”<sup>132</sup>

The Inquiry has received evidence relating to consent for blood transfusions for those with sickle cell anaemia. For example, Trevor Clarke’s partner, Enid, who came to the UK in the 1960s with her mother as part of the Windrush generation, received regular blood transfusions. She was infected with Hepatitis C and died in 1999:

*“As for the ‘general’ risks of blood transfusions given, she was aware of the long-term effects but she needed them to maintain recovery from, or stave off recurring Sickle Cell crises. It was difficult, especially knowing the more blood transfusions given, the more the iron levels would have an effect on liver, heart, kidneys etc ... Regular blood transfusions were the norm for dealing with Sickle Cell Anaemia, therefore consent was not sought.”*<sup>133</sup>

Oleander Agbetu’s mother, Agatha, was diagnosed with Hepatitis B which she was infected with through blood transfusions for sickle cell anaemia: “*It is very likely that Mum was treated without her explicit, informed consent because of her character – she would have said yes to everything because she had complete faith in the medical profession.*”<sup>134</sup>

## **Malignant haematology**

Patients with leukaemia, lymphoma (Hodgkin and non-Hodgkin) or multiple myeloma often required a significant number of transfusions. Professor Anthony Goldstone, consultant haematologist at the University College London Hospital from 1976 to 2011, describes that many of the patients he treated would “*not have survived either their diseases or their treatments*” without transfusions.<sup>135</sup>

Patients with leukaemia, particularly those who were elderly and those at risk of heart failure, were often transfused with whole blood or red cell concentrates. Platelet concentrates were

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131 Written Statement of Professor Dame Sally Davies para 14, para 16, para 17 WITN6929001

132 Written Statement of Professor Dame Sally Davies para 30, para 57, para 22 WITN6929001

133 Written Statement of Trevor Clarke paras 35-36, para 40 WITN5416001

134 Written Statement of Oleander Agbetu para 31 WITN4729001

135 Written Statement of Professor Anthony Goldstone p5 WITN6971001

given to control bleeding associated with thrombocytopenia or because platelet levels had dropped below a threshold level.<sup>136</sup>

As with other medical specialities, the transfusion threshold fell “*successively, over the years*”. Patients with lymphoma required fewer red cells and platelet transfusions as there was “*less marrow involvement by disease*”. However, treatment with aggressive chemotherapy did involve transfusion. Patients with myeloma frequently required red cells but rarely platelets. This was because the anaemia was due to marrow infiltration and expanded plasma volume.<sup>137</sup>

Professor Goldstone described that “*there has been a very appropriate and increasing tendency over the past 30 years to think twice about the administration of any blood product on grounds of risk.*”<sup>138</sup>

However, many individuals have told the Inquiry that they were not informed of the risks of blood transfusions. Lynne Hill was infected with Hepatitis C through transfusions given during leukaemia treatment. She said “*I was given pints and pints of blood, but I was never told about the risk of infection or asked to consent. It did keep me alive so looking at it that way, if I had been told that being given blood which might infect me but would keep me alive was the only option, I may have taken it. But then it would have been my choice but I was never informed or consulted about risks.*”<sup>139</sup>

Fiona Crawford was diagnosed with acute myeloid leukaemia and underwent chemotherapy at the Edinburgh Royal Infirmary. She says she “*was constantly given blood and blood products as supportive treatment ... I was not given any information or advice about the risks of being exposed to the infection. I was in a life or death situation and needed blood to keep me alive. You trust medical staff to know what they are doing. I was infected with hepatitis C.*”<sup>140</sup>

Mary Heath’s husband, Robert, was infected with Hepatitis C during treatment for acute myeloid leukaemia and explains “*We were told that Robert would be given blood products as part of his treatment for Acute Myeloid Leukaemia. It was a do or die situation, he needed to have the transfusions as part of his treatment otherwise the Leukaemia would kill him. We left it in the hands of the experts.*”<sup>141</sup>

Paul Mouncey’s wife, Jane, was diagnosed with a rare blood cancer and required regular blood transfusions, through which she was infected with Hepatitis C. She required the transfusions “*as the chemotherapy had destroyed all of her bone marrow ... Nothing was*

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136 Written Statement of Professor Anthony Goldstone p9 WITN6971001

137 Written Statement of Professor Anthony Goldstone p9 WITN6971001

138 Written Statement of Professor Anthony Goldstone p10 WITN6971001

139 Written Statement of Lynne Hill para 8 WITN0538001

140 Written Statement of Fiona Crawford paras 6-8 WITN2108001

141 Written Statement of Mary Heath para 42 WITN3341001



*made clear about the screening of blood products. We were never given any indication that there was a risk from the transfusion.*<sup>142</sup>

## Alternatives to transfusion

Many of the alternatives to blood transfusions used in practice today only became widespread in the 2000s. However, some of the simplest and most effective means – iron supplements and tranexamic acid – were available well before the 1970s, and it has always been an option to decline to transfuse (even though there are many cases in which it is plainly essential to keep a person alive, there are others where transfusion is not essential but is optional, as in “topping up” a patient).

It is unclear, particularly in relation to iron supplements and tranexamic acid, why they were not used more widely much earlier than they have been.

### Iron

Iron is responsible for the colour of blood. It is an essential element in the formation of haemoglobin, and if it is in short supply within the body the blood cannot carry as much oxygen as is needed.<sup>143</sup> Anaemia follows. Thus where red blood cells are lacking, the body needs a supply of available iron to rectify the shortage. Iron in an assimilable form was a cheap and easily available therapy that could be used to treat anaemia. In particular, iron was “*always*” an alternative for the treatment of anaemia following childbirth. The disadvantages of the administration of iron were that it was slower to have a beneficial impact than giving blood, and some patients poorly tolerated its administration. In recent years ferric carboxymaltose infusions (“Ferinject”) have been increasingly used and are offered in some units as an alternative to transfusion.<sup>144</sup>

The Inquiry has received a number of statements from women who query whether they should have been given iron instead of a blood transfusion. For example, Mary Barr was infected with Hepatitis C through a transfusion following a post-natal haemorrhage after the birth of her first child in 1991. She says:

*“I had been anxious during my pregnancy that I was becoming anaemic but the GP and others responsible for my antenatal care refused to put me on an iron supplement or do an extra blood test to check for anaemia. They waited for the date of the routine test which showed that I was indeed anaemic. I started taking iron but because I was diagnosed so late in my pregnancy, it was too late for iron tablets to take effect ... [After the birth] I was told that I required a blood*

142 Written Statement of Paul Mouncey para 12, para 16 WITN0904001. See also the response by Dr Lucie. Written Statement of Dr Norman Lucie para 4 WITN7116019

143 The solution is not to give enough for iron to be in surplus, for iron in excess quantity is toxic. The necessary moderation in the amounts of iron in the body is one of the reasons why plasma (which does not need iron) is much more readily and speedily replaced within the body than red blood cells, for which iron is critical.

144 Written Statement of Dr David Bogod p14 WITN6975001

*transfusion ... I asked the attending nurse if there was a possibility of catching an infection during the blood transfusion, or if the blood had been screened ... I was told point blank that there was nothing to worry about as all blood was now carefully screened ... Had I been given the slightest idea of the risk involved and given a choice I would far rather have felt 'run down' or unwell for months than have the transfusion, as I am sure that having a transfusion was not 'life-saving' in my case but more of a 'short-cut' to a return to full strength."*

Mary's haemoglobin levels were monitored more closely in her second pregnancy, at her insistence, and she was prescribed iron tablets at an earlier stage in her pregnancy.<sup>145</sup>

Maureen Harrison was infected with Hepatitis C when she received a blood transfusion after the birth of her second child in 1978: *"The midwife told me that I could stay in hospital and have a transfusion of two units of blood. She said that the alternative would be to take six months of iron tablets. She advised that it would be better to stay overnight and have the transfusion, so I agreed to have the transfusion of blood. My haemoglobin levels were 8.9 and I was transfused with two units of blood."*<sup>146</sup>

Another woman was infected with Hepatitis C following the birth of her third child in 1987 and says:

*"I recall the Doctor/Consultant asking if I was always this pale. They did a blood test and an hour or so later the same doctor came into the room and said I needed an immediate blood transfusion, which I refused initially. I asked why I couldn't have iron tablets instead, but was told by the same doctor if I did not have the transfusion, given the rate I was bleeding I would have a cardiac arrest and die. She asked why I was so against it ... She assured me 'You have nothing to worry about as all the blood is now heat treated.'" <sup>147</sup>*

This was one of four cases where the Inquiry has evidence of a patient being told that blood is safe because it is heat-treated. Three were cases from the Yorkshire area, though different hospitals.<sup>148</sup>

The statement is false, since red blood cells for transfusion cannot be heated without the heat destroying their effect. The statement was deceptive in at least one of the three Yorkshire cases;<sup>149</sup> but it represents a serious failure of understanding in the other two, if it was not actually deceptive there too. This is because in one of these – the case of Darren Rawson<sup>150</sup>

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145 Written Statement of Mary Barr paras 6-7 WITN0241001

146 Written Statement of Maureen Harrison paras 2-3 WITN1896001

147 Written Statement of ANON paras 8-9 WITN7258001

148 Written Statement of Lesley McEvoy paras 6-7 WITN1934001, Written Statement of Darren Rawson para 4 WITN1963001, Written Statement of ANON para 9 WITN7258001. The fourth relates to Yorkhill Hospital in Glasgow. Written Statement of Katrina Hughes para 3 WITN0377001

149 Lesley McEvoy's case is reviewed in the chapter on *Document Destruction*. Written Statement of Lesley McEvoy paras 6-7 WITN1934001

150 Darren Rawson said in his oral evidence that he thought he received "About two pints" of blood. Darren Rawson Transcript 12 June 2019 p73 INQY1000018

– he received a letter from the chief executive of Hull and East Yorkshire Hospitals NHS Trust which said: “*In England and Wales blood began to be heat treated to destroy any viruses during 1985 and slightly later than this in Scotland. According to our records you were given blood in 1988 and this was done in the belief that the blood from the transfusion service was safe and heat treated.*”<sup>151</sup>

This letter was written in 2015. The chief executive when writing it repeated an understanding he had been given by one of his consultants. It is likely that there has been a confusion (in this case) between heat treatment of blood products (which not only **can** be done but was necessary in the interests of safety) and heat treatment of blood for transfusion (which simply **cannot** be done). It is alarming that a fundamental lack of understanding or thought, an elementary error, existed at all in 1988, when the transfusion was given, and even more disturbing that this view should have persisted, for at least 27 years, and then should have been said, or (more likely) repeated, by a consultant.

It is a failure of medical education and training that it should have done so; the patient deserved better.

### Tranexamic acid

Tranexamic acid is a medication which treats or prevents excessive blood loss. It was invented in the early 1960s.<sup>152</sup> Fibrinolysis is a normal physiological process whereby clots are broken down in the body. If, however, the body clots with difficulty, or there is significant blood loss, it will aid recovery if the breakdown of any clot can be slowed down. This is what tranexamic acid does: it is an anti-fibrinolytic. It can be taken orally or given by injection. It is effective in major trauma.<sup>153</sup> It “*cuts surgical bleeding by about one third to one quarter and has an excellent safety profile.*”<sup>154</sup>

Tranexamic acid was sometimes used in the 1970s in certain settings such as dental extractions and peri-operative settings for the treatment of people with bleeding disorders.<sup>155</sup> However, the evidence for the benefit of using tranexamic acid to reduce bleeding in surgical patients was not available until “*many years later*”.<sup>156</sup> Evidence that tranexamic acid prevents surgical bleeding, reducing the need for blood transfusion, has only been available

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151 Written Statement of Darren Rawson para 4 WITN1963001, Letter from Chris Long to Darren Rawson 24 February 2015 WITN1963006. The letter from Chris Long specifically referred to the transmission of viruses via blood transfusion.

152 Written Statement of Professor Ian Roberts para 2 WITN7310001

153 Expert Report to the Infected Blood Inquiry: Bleeding Disorders and Blood Disorders January 2020 p17 EXPG0000002

154 Written Statement of Professor Ian Roberts para 1 WITN7310001

155 Expert Report to the Infected Blood Inquiry: Bleeding Disorders and Blood Disorders January 2020 p33 EXPG0000002

156 Written Statement of Professor Michael Murphy para 36 WITN7001001

*“for over a decade.”*<sup>157</sup> From around 2000 tranexamic acid was used regularly in several areas of surgery.<sup>158</sup>

Tranexamic acid is now much more widely available and there are NICE guidelines on its use.<sup>159</sup> However, a survey of 98% of NHS Trusts in England undertaken in October 2013 found that 27% of Trusts were not using tranexamic acid for trauma patients, and 30% were not using tranexamic acid for surgical patients.<sup>160</sup> In 2021 the National Comparative Audit of Blood Transfusion programme found that the NICE Quality Standards on tranexamic acid are not being complied with: such compliance would probably prevent *“over 15,000 major surgical bleeds, save 33,000 units of blood and save many millions of pounds for the NHS each year.”*<sup>161</sup>

To increase the use of tranexamic acid in surgery, Professor Ian Roberts has established an implementation group with representation from the Royal College of Surgeons of England, the Royal College of Anaesthetists and the Royal College of Physicians to ensure that *“all surgeons and anaesthetists are aware of the benefits of tranexamic acid use in surgery”* and that consideration of the use of tranexamic acid is included on the safe surgery checklist for all NHS hospitals. Professor Roberts reflected that *“changing practices in the NHS is hard, especially so in this case because tranexamic acid is a cheap generic drug and there is no profit motive for pharmaceutical companies to promote and implement it.”* He describes the low usage of tranexamic acid as a *“market failure”* and that compliance with the NICE guidelines on tranexamic acid is *“poor and there are no sanctions for non-use.”* The consequence of this is that patients receive *“worse outcomes and are unnecessarily exposed to the risks of blood transfusion but there are no consequences for doctors and hospitals that fail to provide recommended care.”*<sup>162</sup>

Professor Roberts told the Inquiry that despite his many letters to UK Ministers of Health, the Chief Medical Officer (“CMO”), the Care Quality Commission, the Joint United Nations Programme on HIV/AIDS, the World Health Organization and many others highlighting the role of tranexamic acid in reducing bleeding, there has been *“no action in response.”* Writing in October 2022 after NHSBT for the first time went to amber alert status due to low red cell stock levels, he said that *“only in the past few months, after NHSBT declared a national blood shortage have the relevant authorities shown any interest.”*<sup>163</sup> Yet the following year

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157 Written Statement of Professor Ian Roberts para 1 WITN7310001

158 Written Statement of Dr Jonathan Wallis p24 WITN6982001

159 NICE recommended its use in 2015 and 2016. NICE Guideline on Blood Transfusion 18 November 2015 pp22-23 RLIT0001793, NICE Quality Standard on Blood Transfusion 15 December 2016 pp8-9 RLIT0001794

160 NHS National Blood Transfusion Committee *Patient Blood Management* 26 June 2014 p4 WITN7001027, Written Statement of Professor Ian Roberts para 1 WITN7310001

161 Letter from Professors Murphy and Roberts to Sir Brian Langstaff 16 November 2022 p2 WITN7310002. The letter includes further details on the steps being taken to address this.

162 Written Statement of Professor Ian Roberts paras 1-2 WITN7310001

163 Written Statement of Professor Ian Roberts para 2 WITN7310001

he was very disappointed to find the 2023 audit of the NICE Quality Standards produced near identical results to the 2021 audit on tranexamic acid.<sup>164</sup>

### Autologous transfusion

Autologous red cell transfusion is where a patient's own red cells are used for transfusion, rather than the red cells donated by another person. There are three types of autologous transfusion. The first is acute normovolaemic haemodilution where a patient's blood is collected pre-operatively and the blood collected is replaced by intravenous saline solution. The second is perioperative red cell salvage: a patient's blood is collected from the operation site or wound and returned through a vein in the same way as any other red cell transfusion. This method requires specialist equipment and staff, and cannot be used in cases of bacterial infection or malignancy. It is also possible for blood to be collected from the wound after the operation and then transfused. Third, in preoperative autologous donation ("PAD") blood is taken from the patient prior to surgery<sup>165</sup> and then transfused peri- or post-operatively. The date of elective surgery must be known and PAD may not be appropriate in cases involving cardiac disease, cerebrovascular disease, low body weight or a patient with poor veins. As at 2000, there was no published data about the frequency of autologous transfusion in the UK.<sup>166</sup> Guidelines produced by the British Committee for Standards in Haematology, published in 2006, did not recommend the use of PAD unless the "*clinical circumstances are exceptional*."<sup>167</sup>

Professor Steer describes investigating the possibility of autologous blood transfusion for women having elective caesarean sections in the 1980s and early 1990s. He was told by the haematology department that it was possible however "*it was strongly discouraged by them*" because blood donated by a patient had not been screened and therefore would need to be stored separately, and that if the woman needed more blood due to a major haemorrhage the one or two units collected antenatally would not be enough. He has no recollection if any of his patients pursued autologous blood transfusion and it was only considered appropriate in cases involving Jehovah's Witnesses or for women with very unusual antibodies which made finding matched blood very difficult. He states that there were "*no obvious alternatives to blood transfusion in the 1970s through to the 1990s that seemed appropriate in maternity care*."<sup>168</sup>

The evidence suggests that when autologous transfusions were available, they were not frequently used. For example, in the 1990s, "*stimulated*" by the Better Blood Transfusion initiative, the Northern Irish Blood Transfusion Service offered an autologous deposit service. However, the uptake was never more "*than minimal*." In practice, it was only really

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164 Letter from Professor Murphy to Sir Brian Langstaff 1 November 2023 p2 WITN7310003

165 Between a month and six weeks before.

166 Dr Julia Taylor *Autologous Transfusion* 20 June 2000 p2, p4 NHBT0000033\_011

167 Boulton and James *Guidelines for policies on alternatives to allogeneic blood transfusion 1 Predeposit autologous blood donation and transfusion* 14 December 2006 p1 WITN3456004

168 Written Statement of Professor Philip Steer p9, pp21-22 WITN6977001



used for bone marrow donor volunteers. Dr Morris McClelland has told the Inquiry that the experiences of trying to *“implement or pilot these technologies demonstrated that there were so many practical disadvantages as to preclude their use on a large scale.”*<sup>169</sup>

The picture was similar in Scotland. Dr Gillon was part of the first pre-deposit autologous donation service in the UK, which began in 1987. This was the only Scottish centre to do so. This service was mainly for patients undergoing elective hip replacements. He carried out a controlled clinical trial of autologous cell salvage in cardiac surgery and was a member of the Working Party on Autologous Transfusion from 1992 to 1993 and its chairman from 1994 to 1996.<sup>170</sup> This working party produced guidelines for pre-deposit autologous transfusion in 1993.<sup>171</sup> Dr Gillon states that from the late 1990s that there was *“really very little demand”* for the procedures and in Scotland the autologous transfusion service was *“reduced to a single provider – Glasgow and West of Scotland BTS [Blood Transfusion Service]”*. By 1996 only 133 patients had been referred, resulting in 90 patients donating 171 units of blood for their own use. In 1997 the number of referrals doubled *“as a result of an enthusiastic anaesthetist, only to fall back again when we switched to a system based on self-referral by patients who had been provided with information explaining the availability of this procedure.”*<sup>172</sup>

A service for autologous blood transfusion was implemented in Newcastle at the Freeman Hospital in the mid to late 1980s to early 1990s, but:

*“by the time of the operation the patients were inevitably anaemic unless they had also received erythropoietin,<sup>173</sup> a practice used elsewhere but rarely to my recollection in the UK for reasons of expense and possible side-effects. Postoperatively, it was not uncommon for the stored units not to be used. Some of the risks of transfusion such as bacterial infection remained. During storage, which by the nature of the programme is likely to be longer than for voluntary unrelated donor red cells, there is some loss of cells and some loss of function of cells. The effects of these are uncertain but not beneficial. Patients who had given autologous blood pre-operatively were more likely to require per-operative transfusion because they arrived at surgery more anaemic than if they had not donated blood.”*<sup>174</sup>

169 Written Statement of Dr Morris McClelland p106, p108 WITN0892001

170 Written Statement of Dr Jack Gillon para 12, paras 150-151 WITN6987001, Bell et al *A controlled trial of intra-operative autologous transfusion in cardiothoracic surgery measuring effect on transfusion requirements and clinical outcome* Transfusion Medicine 1992 pp295-300 RLIT0002411

171 British Committee for Standards in Haematology Blood Transfusion Task Force *Guidelines for autologous transfusion. I. Pre-operative autologous donation* Transfusion Medicine 1993 BSHA0000017\_021, British Committee for Standards in Haematology Blood Transfusion Task Force *Guidelines for autologous transfusion. II. Perioperative haemodilution and cell salvage* British Journal of Anaesthesia 1997 RLIT0000815

172 Written Statement of Dr Jack Gillon para 149, para 151 WITN6987001, Ribbons et al *Increased Uptake of Autologous Pre-Donation in Elective Orthopaedic Surgery* Transfusion Medicine 1999 RLIT0000819

173 A hormone which stimulates red blood cell production.

174 Written Statement of Dr Jonathan Wallis para 51, para 96 WITN6982001

Uptake was “*not high*” and “*it became apparent that the practice was of very limited if any benefit to the patient*”. This was discontinued in the 1990s.<sup>175</sup>

The Inquiry has received evidence from patients who requested autologous transfusions. For example, Marlene Neve underwent a hysterectomy in February at the Burnley General Hospital, received a post-operative blood transfusion and was infected with Hepatitis C. She was working as a radiographer at the hospital at the time and was aware of the risks posed by HIV so she asked the consultant prior to surgery if she could donate her own blood in advance of the procedure, should a transfusion be necessary. She was told that she was not fit enough and that her haemoglobin levels were too low.<sup>176</sup> Other patients say when they asked about the use of their own blood, they were not given any proper explanation.<sup>177</sup>

Overall, autologous transfusions were not available for patients throughout the UK during the 1970s and 1980s. From the 1990s such transfusions were only available in a minority of centres and even they often did not inform patients about the service.<sup>178</sup> They were not a viable and workable alternative for patients in the UK seeking to avoid blood or blood components, partly because of this lack of availability, but also because it came increasingly to be thought that pre-operative autologous transfusion was ineffective, because taking blood from the patient depleted their haemoglobin levels, which would have to be replaced naturally before their operation was scheduled. This took longer than the time elapsing before the operation (in any event, any blood taken in advance of the operation would have around 5 weeks “shelf-life” at a maximum – and that period was simply too short for the body to replace the lost haemoglobin). The result was the patient could become anaemic and thus require a further transfusion (ie a further one not of their own blood) during surgery. This contrasts with the position in the US and Europe where, as a “*paid for*” service, pre-operative autologous donation was used widely from the mid 1980s “*when there was increasing concern about the safety of donated blood*”. However its use declined because it was shown not to be effective because, as described, the patient’s haemoglobin level recovered “*little, if at all*” between their blood being collected and their operation.<sup>179</sup>

## Red cell salvage

Red cell salvage is a subset of autologous transfusion: a patient’s own red cells are removed and then given back to them.<sup>180</sup> It was not widely available in the 1970s to 1990s. It required

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175 Written Statement of Dr Jonathan Wallis para 51 WITN6982001

176 Written Statement of Marlene Neve paras 3-10 WITN0936001

177 For example Written Statement of ANON para 7 WITN0324001

178 Research Unit of the Royal College of Physicians National Audit of the Clinical Blood Transfusion Process 1998 p6 NHBT0042247

179 Harrison *Getting Your Own Back – An Update on Autologous Transfusion* Blood Matters 2004 p7 SCGV0000203\_048, Written Statement of Dr Jean Harrison paras 543-557 WITN7046001. Dr Harrison said she was initially enthusiastic about pre-deposit autologous transfusion but came to the view that “*only intra-operative cell salvage is a useful procedure*”.

180 For this reason, it is often the preferred treatment for Jehovah’s Witness patients. Written Statement of Dr Jean Harrison para 546 WITN7046001

specialist equipment and knowledge and was not commonly used.<sup>181</sup> Red cell salvage is not appropriate in all types of procedures, for example, in bowel surgery or cancer operations as the blood might be contaminated. However, it is particularly suitable in cases of cardiac and orthopaedic surgery as well as in major abdominal/thoracic trauma surgery and liver, heart and lung transplants.<sup>182</sup>

The Morriston Hospital in Wales was an early adopter of the technology. In around 1989 a cell salvage autotransfusion device was used in intra-renal aortic surgery. A three-year audit found that the device led to a decrease in the volume of red cell transfusion administered to patients. From 1992 it was used in other surgeries, including knee replacement surgery. The use of allogeneic red cell transfusion in total knee replacement surgery decreased from 82% to 27% and then to 7% due to “*the introduction of a transfusion trigger and the use of cell salvage autotransfusion.*” Dr Thomas became a key proponent of this technique, writing and contributing to the guidelines in this area.<sup>183</sup>

Since the 1990s red cell salvage has been more widely available. The Edinburgh Royal Infirmary undertook a study of intraoperative cell salvage in cardiac surgery, where blood shed during surgery was salvaged by suction into a cell separator, the red cells concentrated, washed in saline and returned to the patient. One unit of homologous transfusion was saved per patient “*but the procedure was shown to be feasible and safe and it became an accepted part of surgical practice in a number of departments throughout the UK.*”<sup>184</sup>

Red cell salvage was introduced at the Chelsea and Westminster Hospital in the early 2000s. By 2006 the UK Obstetric Anaesthetists Association had established that cell salvage was used in 38% of maternity units.<sup>185</sup>

A survey of 98% of NHS Trusts in England undertaken in October 2013 found that there is “*patchy*” use of intra-operative cell salvage, with 55% of Trusts using it for orthopaedic surgery.<sup>186</sup>

Cell salvage could have been introduced earlier and the delay was largely due to the “*obvious resource implications*” in terms of the need for cell salvage machines to be purchased and someone employed to operate the machine.<sup>187</sup>

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181 Written Statement of Professor Michael Murphy para 36 WITN7001001

182 Written Statement of Dr Jean Harrison para 545 WITN7046001

183 Written Statement of Dr Dafydd Thomas paras 38-43, para 61 WITN6973001

184 Written Statement of Dr Jack Gillon para 152 WITN6987001

185 Written Statement of Professor Philip Steer para 23 WITN6977001

186 NHS National Blood Transfusion Committee *Patient Blood Management* 26 June 2014 p4 WITN7001027

187 Written Statement of Dr Jean Harrison para 559 WITN7046001

## What steps were taken to reduce unnecessary blood transfusions?

Although guidelines were produced recommending caution in the use of blood, the clinical practice on the ground tended towards over-use. Significant steps to address the use of unnecessary blood transfusions were not taken until the 1990s and beyond. It is unclear why not. There does not appear to be any greater rationale for the delay in implementing steps to reduce the unnecessary use of blood than insufficient impetus from medical, academic and governmental organisations to address the issue. It appears that one of the driving factors for change was the new legislative landscape with the Consumer Protection Act 1987 and the introduction of the European Directive on blood, which led senior individuals working in the transfusion services to focus on the issue of blood transfusion.<sup>188</sup>

Measures were however ultimately taken. These are dealt with below, in turn. They are the creation of specialist working groups and committees (leading to greater awareness amongst practitioners, and ultimately to haemovigilance through SHOT, and better practice), auditing, maximum blood ordering schedules, hospital transfusion practitioners, HTCs, SHOT and finally the Better Blood Transfusion initiative. These measures have been set out in a broadly chronological order.

### JPAC

In the late 1980s new committees and working groups were created which were concerned with blood transfusion.

The Joint United Kingdom Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (“JPAC”) was established in 1987. It was previously known as the UK Blood Transfusion Service (“UKBTS”)/NIBSC Executive Committee. JPAC has two roles. The first is to prepare detailed guidelines for the UK blood transfusion services. These are known as the Red Book and were first published in 1989. The second is to act as an advisory committee by reporting to the medical directors of the four UK blood services.<sup>189</sup> JPAC is made up of blood transfusion experts, microbiologists, epidemiologists and public health experts.

Seven Standing Advisory Committees (“SACs”) now feed into JPAC.<sup>190</sup> The membership of JPAC consists of the chair of each of these SACs, the medical directors of the four UK blood services and the director of the National Institute of Biological Standards and Controls.<sup>191</sup>

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188 See for example: Letter from Geoffrey Schild to Dr William Wagstaff 24 February 1987 NHBT0000127\_002, Written Statement of Dr William Wagstaff para 293 WITN6988001

189 Written Statement of Dr Lorna Williamson para 283 WITN0643010

190 There are SACs on Blood Donation, Transfusion-Transmitted Infection (“SACTTI”), Blood Components (“SACBC”), Immunohaematology, Tissues and Cells, Information Technology and Clinical Transfusion Medicine. The last produces, in conjunction with the British Society for Haematology, the Handbook of Transfusion Medicine provided to hospital staff.

191 Written Statement of Dr Lorna Williamson para 284 WITN0643010

## Standing Advisory Committee on Transfusion Transmitted Infections (“SACTTI”)

One of the SACs that feeds into JPAC is SACTTI.

Its origins lie in 1988. In that year the UK Advisory Committee on Transfusion Transmitted Diseases (“ACTTD”) was set up by Dr Harold Gunson, who was also its first chair.<sup>192</sup> The purpose of this group was to provide expert advice for the transfusion services on virally transmitted disease. It originated because Dr Gunson did not himself have specific expertise in the virological safety of blood and transfusion-transmitted infections.<sup>193</sup>

At very much the same time, another advisory committee – the Advisory Committee on the Virological Safety of Blood (“ACVSB”) – was set up by the Department of Health. Though the ACTTD and the ACVSB overlapped in that both were concerned with infections transmissible by blood, the ACVSB gave advice on major policy issues to ministers whereas the ACTTD – consisting of experts from within the blood services – tended to consider the practical implementation of policies. The functions of these two committees continued much as before, though their remit extended a little: both had name changes in the 1990s which represented these extensions. Thus the ACVSB was superseded by the Advisory Committee on the Microbiological Safety of Blood and Tissue (“MSBT”);<sup>194</sup> and the ACTTD by SACTTI.<sup>195</sup> There remained a lack of clarity about how the committees should work together, in part because MSBT discussions were confidential.<sup>196</sup>

Dr Robinson told the Inquiry that from her experience as medical director of the National Blood Authority (“NBA”) from 1994 sitting on MSBT: *“As far as I am aware the ministers generally did take the advice of the MSBT; the difficulty faced was getting any recommendations put forward to be approved by the Chair Jeremy Metters but once endorsed by the Chair then it was rare that ministers disagreed with those recommendations.”*<sup>197</sup>

SACTTI then began to provide advice to all of the national blood transfusion services. It reported to the UKBTS and NIBSC liaison committee. This was so that there could be a standardised set of practices on blood transfusion throughout the UK.<sup>198</sup>

Part of SACTTI’s remit involved and involves commissioning, conducting and coordinating trials for new technology involved in screening blood.<sup>199</sup> It is made up of doctors, scientists and academics with knowledge in transfusion-transmitted infections, *“their detection and*

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192 Letter from Dr Robinson to Dr Metters 20 September 1995 DHSC0006906\_013

193 Written Statement of Dr Angela Robinson paras 503-504, paras 539-540 WITN6926001

194 Department of Health proposal for the MSBT SCGV0000210\_096. In 2008 the advisory committee on Microbiological Safety of Blood, Tissues and Organs (“MSBTO”) would be superseded in turn by the advisory committee on the Safety of Blood, Tissues and Organs (“SaBTO”).

195 In 1993 when the National Blood Authority was set up. Written Statement of Dr Angela Robinson para 504 WITN6926001

196 Written Statement of Dr Lorna Williamson paras 286-287, para 753 WITN0643010

197 Written Statement of Dr Angela Robinson para 498 WITN6926001

198 Written Statement of Dr Angela Robinson para 504, para 517 WITN6926001

199 Written Statement of Dr Angela Robinson para 508 WITN6926001. Meetings take place quarterly but there are also specific topic meetings which could take place on an as and when basis. Written Statement of Dr Angela Robinson para 523 WITN6926001. These topics have included the virological



*prevention, epidemiology and public health.*<sup>200</sup> Its main function today, as part of JPAC, is to produce chapters in the Guidelines for the UK Transfusion Services.<sup>201</sup> This includes detailed guidance on the microbiological testing of donors in blood centres such as pool size, positive screening and reinstatement of donors.<sup>202</sup>

SACTTI's recommendations to the blood services are subject to funding decisions and there has never been a formal, direct link to the Department of Health.<sup>203</sup> Therefore, in the 1990s if a regional health authority was not prepared to fund a recommendation made by SACTTI *"it was then difficult to implement it"*.<sup>204</sup>

## Auditing

An effective method of reducing the unnecessary administration of blood was the introduction of audits. A study into blood usage in the Tayside region of Scotland in 1986 noted that the *"auditing of blood ordering practices is a much neglected area in surgery."*<sup>205</sup> In the 1990s there was a move towards undertaking audits at individual hospitals and on a national scale. Audits were also undertaken at RTCs.<sup>206</sup> Audits were usually surveys recording blood use with trends being analysed per hospital or speciality. This often resulted in a fall in blood component usage: for instance, at the Freeman Hospital in Newcastle, the introduction of auditing and surveys was in part responsible for a fall in red cell usage of around 30% over a 20-year period despite an increase in clinical activity.<sup>207</sup> It appears that this was because of competitiveness between doctors to avoid being the one who used too much blood; if their peers were using less blood than them, then colleagues reduced their own blood usage.<sup>208</sup>

In September 1995 the NHS Executive funded a national audit initiative relating to two blood transfusion protocols. First was an institutional audit for blood transfusion practice in 50 hospitals throughout the four nations of the UK; second, an audit of the documentation of blood transfusion in 23 hospitals.<sup>209</sup> The audit demonstrated that there was *"considerable*

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safety of plasma and the epidemiology of Hepatitis C. Minutes of SACTTI meeting 3 March 1995 NHBT0017284, Minutes of SACTTI meeting 13 February 1995 p3 NHBT0000088\_009

200 Written Statement of Dr Lorna Williamson para 274 WITN0643010

201 Written Statement of Dr Lorna Williamson para 271 WITN0643010

202 Written Statement of Dr Lorna Williamson para 271 WITN0643010

203 Written Statement of Dr Lorna Williamson para 279 WITN0643010. The Advisory Committee on Virological Safety of Blood ("ACVSB") did have a direct link with the Department of Health. Written Statement of Dr Lorna Williamson para 278 WITN0643010

204 Written Statement of Dr Angela Robinson para 537 WITN6926001

205 Pathi et al *It's Scotland's blood, so why waste it?* Journal of the Royal College of Surgeons of Edinburgh 1987 p1 RLIT0001020

206 See the evidence of Dr Robinson about the efforts of Dr Gunson, Dr Timothy Wallington and Dr Patricia Hewitt to introduce audits at Bristol, North London, Tooting and Cambridge RTCs. Written Statement of Dr Angela Robinson para 40 WITN6926001

207 Written Statement of Dr Jonathan Wallis para 144 WITN6982001

208 Dr Jonathan Wallis Transcript 24 February 2022 pp40-41 INQY1000187

209 Written Statement of Professor Michael Murphy para 80 WITN7001001

*variation in the performance of standard procedures in relation to the administration of blood*". The study described the "level of shortfall in practice" as "alarming".<sup>210</sup>

In 2001 the CMO's National Blood Transfusion Committee ("NBTC") was established in England.<sup>211</sup> The NBTC first met in December 2001 and continues to meet twice a year.<sup>212</sup> One of its functions is to conduct national audits each year. The work of the NBTC has demonstrated that 20-30% of transfusions are given outside the recommendations found in national guidance.<sup>213</sup> This therefore remains concerning.

### Maximum Blood Ordering Schedules

Maximum Blood Ordering Schedules ("MBOS") are a mechanism for deciding how many units of blood should be ordered and set aside for a specific operation. Where an MBOS was in place, the blood bank would be informed of the operation for which blood was sought, and would then crossmatch the number of units required for that procedure according to the schedule. This took the place of the surgeon always specifying the number of units required.<sup>214</sup>

Professor Stanislaw Urbaniak, Director of the Aberdeen and North East Blood Transfusion Service, met clinicians from specialities at the Aberdeen Royal Infirmary and agreed maximum surgical blood ordering schedules (except for open-heart surgery, major gastrointestinal bleeding, major obstetric haemorrhage and major trauma). This led to a reduction in the number of "unnecessary" whole blood transfusions as well as to a reduction in the total number of transfusions per operation "reducing the risk of adverse events associated with blood transfusions."<sup>215</sup> Dr Galea, who worked at Aberdeen from 1984 to 1993, describes that MBOS led to clinicians becoming "much more confident" about using less blood.<sup>216</sup>

In 1990 the British Committee for Standards in Haematology issued guidelines for the implementation of MBOS.<sup>217</sup> In January 1998 the Royal College of Physicians identified that of the 50 hospitals audited in their "National Audit of the Clinical Blood Transfusion Process", 87% of them had MBOS and in 71% of these, they were regularly reviewed.<sup>218</sup> However, it is unclear whether MBOS were written to comply with national guidelines or whether they

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210 Murphy et al *National audit of the blood transfusion process in the UK* Transfusion Medicine 2001 p1, p8 WITN7001018

211 Minutes of National Blood Transfusion Committee meeting 3 December 2001 p1 DHSC0038528\_050

212 Written Statement of Professor Michael Murphy paras 99-113 WITN7001001

213 Written Statement of Professor Michael Murphy para 114 WITN7001001

214 Dr George Galea Transcript 3 December 2021 pp23-24 INQY1000168

215 Professor Urbaniak was the regional director for the North East Scotland blood transfusion service 1993-99. Written Statement of Professor Stanislaw Urbaniak para 11, para 80 WITN6960001

216 Dr George Galea Transcript 3 December 2021 pp23-24 INQY1000168. Also Dr Williamson's evidence about East Anglia. Dr Lorna Williamson Transcript 8 December 2021 pp156-158 INQY1000169

217 British Committee for Standards in Haematology Blood Transfusion Task Force *Guidelines for implementation of a maximum surgical blood order schedule* Clinical and Laboratory Haematology 1990 BSHA0000021\_021

218 Research Unit of the Royal College of Physicians *National Audit of the Clinical Blood Transfusion Process* January 1998 p4 NHBT0042247

reflected custom and practice at the time. Nor is it clear that they were fully implemented in practice. A 1991 review commissioned by the Department of Health, on the issue of single-unit transfusions, noted that even where MBOS were in place in individual hospitals, it was not known whether such schedules reflected “*common practice*” and whether they were in fact adhered to.<sup>219</sup> Blood schedules were often based on “*custom and practice, not necessarily top quality evidence about what was best for the patient.*”<sup>220</sup>

In the surgical context, it must also be noted that alongside the use of MBOS, changes in surgical techniques in the later part of the twentieth century, including the increased use of laparoscopic surgery, have also led to a decrease in the amount of blood used.

### Transfusion practitioners

From the 1990s, with an increased focus on improving blood transfusion standards, specific posts of transfusion practitioners were established. For example, at the Morriston Hospital a hospital transfusion practitioner devised a transfusion record chart to aid record keeping and enhancing traceability of transfused components which was then adopted across Wales.<sup>221</sup> Some of the new roles were for transfusion nurses: at the Freeman Hospital in Newcastle this new category of staff was introduced in the late 1990s and one of their roles was to “*follow up and investigate*” reports of adverse reactions to blood transfusions.<sup>222</sup>

Such transfusion practitioners have also been established within NHSBT as part of the “*hospital liaison effort of NHSBT in each NHS region to be made up of medical, scientific and nursing support for hospitals with the aim of delivering better transfusion practice.*”<sup>223</sup>

The establishment of transfusion practitioner roles was promoted by the Better Blood Transfusion initiative in addition to the establishment of Hospital Transfusion Teams.<sup>224</sup> A survey of 98% of NHS Trusts in England undertaken in October 2013 found that only 17% Trusts had less than one full time transfusion practitioner.<sup>225</sup>

### Hospital transfusion committees

Hospital transfusion committees (“HTCs”) were recommended by the British Committee for Standards in Haematology in 1984, in response to a DHSS circular about record keeping and stock control arrangements. Their purpose was to review local blood transfusion policies on a regular basis, and to improve liaison between the haematologist in charge of the hospital blood bank and other clinicians to promote good blood transfusion practice. It was recommended that the terms of reference should include a review of “*blood transfusion*

219 University of Sheffield Medical School Medical Care Research Unit *The Use of Single-Unit Blood Transfusion* November 1991 p6 DHSC0025270

220 Dr Lorna Williamson Transcript 8 December 2021 p157 INQY1000169

221 Written Statement of Dr Dafydd Thomas paras 111-115 WITN6973001

222 Written Statement of Dr Jonathan Wallis para 134 WITN6982001

223 Written Statement of Professor Michael Murphy para 78 WITN7001001

224 The Better Blood Transfusion initiative is discussed below.

225 NHS National Blood Transfusion Committee *Patient Blood Management* 26 June 2014 p3 WITN7001027

‘accidents’”, the optimal use of blood and blood products “based on regular review of blood usage statistics eg cross-match/transfusion ratios for different procedures/clinicians; ‘time-expired’ blood return figures (= potential blood waste)”, and the introduction of new developments in blood transfusion. It was expected that in addition the HTC would have a “continuing educational role in clinical blood transfusion practice.”<sup>226</sup>

By 1989 it seems little had yet happened to give effect to these recommendations. That year, Professor Contreras wrote *New Trends in Blood Transfusion* in which she said:

*“Education of clinicians on the proper use of blood is now becoming an accepted aspect of medical training. Responsible clinicians are re-examining the benefit-to-risk relationship of blood transfusion. However, there is a great deal of ground to be covered since many clinicians consider blood and blood components on the same level as any drug that they prescribe. In some countries, the establishment of Hospital Transfusion Committees has helped a great deal towards a more rational use of blood and it is expected that such committees will be established in more and more hospitals worldwide.”*<sup>227</sup>

In May 1990, Dr Contreras was able to report that HTCs were “now being established” in five major hospitals which the North London Blood Transfusion Centre supplied, following an audit which had shown very disappointing results – for example, only just over 1 in 5 transfusions of fresh frozen plasma which had been given were indicated, and 3 out of every 5 were “definitely not indicated.” She concluded that “improvement in all aspects of transfusion practice is necessary. Education regarding the value of blood components and areas in which their use cannot be justified is particularly needed.”<sup>228</sup>

From these sluggish beginnings in the UK, HTCs were increasingly set up in the 1990s in order to address and oversee issues relevant to transfusion. Though in 1994 fewer than 50% of the 380 hospitals in England and Wales had an HTC, by January 1998 the Royal College of Physicians published a “*National Audit of the Clinical Blood Transfusion Process*”, which found that of 47 hospitals across the UK, 79% had an HTC and audits of transfusion practice had been undertaken at 65% of those.<sup>229</sup> Due to patchy records it has been difficult conclusively to establish when each HTC within a sample across the UK was set up though the broad picture, as indicated by this chronology, is that they had spread to most major hospitals by the end of the 1990s.<sup>230</sup>

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226 Report to the British Society for Haematology on the activities of the British Committee for Standardization in Haematology 7 October 1985 WITN7001004, DHSS HC(84)7 *Blood Transfusion: Record-Keeping and Stock Control Arrangements* March 1984 CBLA0001819

227 Contreras *New Trends in blood transfusion* Biol Clin Hematol 1989 p1 NHBT0057960

228 Letter from Professor Contreras to Dr Hilary Pickles 31 May 1990 pp2-3 NHBT0000189\_142. Emphasis in original.

229 Letter from Dr Robinson to Dr David Winfield 15 August 1996 p2 NHBT0000649, Research Unit of the Royal College of Physicians *National Audit of the Clinical Blood Transfusion Process* 1998 p4 NHBT0042247

230 Counsel Presentation on Hospital Transfusion Committees January 2023 INQY0000423

They had become sufficiently prevalent by 1998 for a Health Services Circular produced by the NHS Executive on 11 December 1998 to set out a series of minimum requirements for HTC's.<sup>231</sup> Similar requirements were issued in Wales, Scotland and Northern Ireland.<sup>232</sup>

As well as being recommended nationally, HTC's were also promoted internationally by organisations such as the World Health Organization.<sup>233</sup>

Throughout the 2000s, blood safety initiatives have continued to emphasise the importance of properly funded and effective HTC's.<sup>234</sup>

HTC's are multi-disciplinary committees which seek to draw together different medical specialities to improve transfusion standards. On the whole, HTC's are a successful creation. They provide a venue to discuss national and local guidelines, as well as local and national audits.<sup>235</sup> They act as an “*essential forum*” for discussion about transfusion matters. They continue to be an important part of maintaining and improving blood transfusion standards.<sup>236</sup>

However, a key issue with their effectiveness is the membership and attendance by clinicians. Some HTC's have struggled to have attendance from members in disciplines other than haematology and transfusion medicine. Pressure of workloads mean that some HTC's have seen patchy attendance levels. Professor Murphy described to the Inquiry that it is a national and international issue that clinicians are “*very stretched and the HTC does not have high priority for them.*”<sup>237</sup>

It is also unclear whether all relevant clinicians were always invited to attend the HTC's. As an orthopaedic consultant, Professor Ribbans was never asked to become a member

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231 The requirements were to:

- promote best practice through local protocols based on national guidelines;
- lead multi-professional audit of the use of blood components within the NHS Trust, focusing on specialities where demand is high such as haemato-oncology and certain surgical specialities;
- maintain a database that allows feedback on performance to all hospital staff involved in blood transfusion;
- promote the education and training of all clinical and support staff involved in blood transfusion;
- have the authority to modify existing blood transfusion protocols and to introduce appropriate changes to practice;
- report regularly to local patient representative groups where appropriate; and
- contribute to the development of clinical governance.

NHS Health Service Circular 1998/999 11 December 1998 p3 NHBT0083701\_002

232 In Scotland, in 1999 a Management Executive letter required the establishment of HTC's. They were noted to be an “*integral part of local arrangements for clinical governance*” and had lines of accountability to the chief executive. In Northern Ireland, in 1999 the Northern Irish CMO issued HSS(MD)3/99 which required Trusts to ensure from March 1999 that HTC's were in place. A circular was also issued in Wales with the same requirement. Letter from Kevin Woods to Colleague 2 February 1999 pp2-4 SCGV0000039\_177, Letter from Dr Henrietta Campbell to Chief Executives of HSS Boards and others 8 March 1999 pp3-5 DHNI0000013\_016, Letter from D Jones to Colleague pp1-2 HSSG0000132\_040

233 World Health Organization *Developing a National Policy and Guidelines on the Clinical Use of Blood* 2001 p21 RLIT0000978

234 Counsel Presentation on Hospital Transfusion Committees January 2023 para 22 INQY0000423

235 Written Statement of Dr Jonathan Wallis para 71 WITN6982001

236 Written Statement of Professor Michael Murphy para 121 WITN7001001

237 Written Statement of Professor Michael Murphy para 121 WITN7001001



of any hospital HTC nor was party to their meetings. In his experience the HTCs at the hospitals he worked at “*did not appear to have any direct relationship with the Trauma and Orthopaedic departments*”.<sup>238</sup>

The success of HTCs has been achieved despite these difficulties. By way of comment, the need for some means to avoid the overuse or inappropriate use of transfusion was necessary, and known to be necessary from before the 1980s. The need for some such process was highlighted in the oral evidence of Professor Dame Marcela Contreras who described how the official guidance in *Notes on Transfusion* had not been faithfully adhered to by clinicians; and how the North London Blood Transfusion Centre under her leadership had conducted audits of blood use, which showed that “*there was a great deal of unnecessary transfusions.*” She had followed this up with the hospital concerned: “*We went to the hospitals and said: Here you are. You know, why, are you using so much -- what’s the justification for you using five units for this type of surgery when this -- or, when the mean is so much and these hospitals are using so little? So some clinicians did not know how much blood they were using.*” With this evidence and experience, she helped to convince the CMO to take action to address the problem, and from these beginnings the Better Blood Transfusion initiative was conceived.<sup>239</sup>

The importance of these measures is shown by her answer when asked what difference it might have made to overall infection levels if doctors had been educated on patient blood management at a much earlier stage. She replied: “*I think it would certainly have made a difference, because, you know, sometimes -- top-up transfusions, for example, were not necessary, and -- well, as our audit showed, yes, it would have made a difference because much less blood was needed in a country. The less blood you give, the less infections you transmit.*”<sup>240</sup>

## SHOT

In November 1996 the Serious Hazards of Transfusion scheme (“SHOT”) was first set up. SHOT is a haemovigilance scheme which collects and analyses adverse events and reactions related to blood transfusions in the UK.<sup>241</sup> It has been described as “*a model for haemovigilance organisations worldwide.*”<sup>242</sup>

Its origins lie in an initiative a couple of years earlier, against a background of well established systems of scrutiny of licensed medicines and licensed biological products.

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238 Written Statement of Professor William Ribbans p14 WITN7707001. Dr Bogod also said that as a consultant anaesthetist practising in Nottingham he did not attend the HTC but a member of his department did. Written Statement of Dr David Bogod p23 WITN6975001

239 Professor Dame Marcela Contreras Transcript 2 December 2021 pp150-160 INQY1000165

240 Professor Dame Marcela Contreras Transcript 2 December 2021 p160 INQY1000165

241 “Haemovigilance” is defined by the World Health Organization as a set of surveillance procedures covering the entire blood transfusion chain, from the donation and processing of blood and its components, through to their provision and transfusion to patients. Written Statement of Dr Alison Cave para 3.3 WITN7477001, Written Statement of Dr Gail Miflin para 1455 WITN0672006, SHOT Terms of Reference November 2001 NHBT0077594\_005

242 Written Statement of Dr Jonathan Wallis para 158 WITN6982001

Though licensed medicines have long had these systems (such as the Yellow Card scheme) to report infections or adverse consequences of taking them, blood was not a licensed product. The Committee on the Safety of Medicine's Yellow Card scheme (which covered serious reactions to drugs and fractionated blood products) thus never included whole blood or red cell concentrates, platelets, fresh frozen plasma or cryoprecipitate. It occurred to Dr Robinson as medical director of the newly formed National Blood Authority that there should be a system for blood components to echo that for licensed medicines.<sup>243</sup>

Accordingly in 1994 she invited Dr Williamson to convene a group to develop a UK-wide reporting system to collate reports of infections and other serious side effects of the transfusion of blood components. There was a wider context to her request: the implementation of an EU Directive on blood and transfusion. This led Dr Robinson and Professor Cash to attend meetings in Europe in preparation for the introduction of the Directive: *"they could see that reporting systems were probably going to be mandated as part of that, so they wanted to get ahead of the game and set something up in the UK."*<sup>244</sup>

Dr Williamson therefore formed a small working group of hospital and transfusion consultants to investigate the risks associated with blood transfusions; these risks go beyond the risks of transfusion-transmitted infections, though they include them.<sup>245</sup>

Although there was a small working group of clinicians and SHOT staff, SHOT's steering group was drawn from a wide range of individuals from the Royal Colleges and professional bodies. It was independent of government.<sup>246</sup> Dr Williamson explains that:

*"We considered it essential that hospital staff felt that SHOT belonged as much to them as to the Blood Services. We, therefore, established a much larger SHOT Steering Group, with representatives of all the professional groups involved in the handling and administration of blood. This was done by inviting the Royal Colleges and professional societies covering nursing, laboratory staff, and medical staff from the major blood-using specialities such as surgery, obstetrics, paediatrics and haematology. We were gratified that, with the exception of the Royal College of Midwives, all professional groups whom we invited agreed to join the Steering Group. There were twelve organisations represented: the Royal Colleges of Anaesthetists, General Practitioners, Nursing, Obstetrics and Gynaecology, Paediatrics and Child Health, Pathologists, Physicians, and Surgeons; the British Blood Transfusion Society, the British Society for Haematology, the Faculty of Public Health Medicine and the Institute of Biomedical Sciences. The Steering Group also included representatives from the UK Blood Services, the PHLS ["Public Health Laboratory Service"] Communicable Disease Surveillance Centre*

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243 Written Statement of Dr Lorna Williamson para 88 WITN0643010

244 Dr Lorna Williamson Transcript 8 December 2021 pp138-139 INQY1000169

245 Written Statement of Professor Mark Bellamy para 4 WITN7312001

246 Professor Mark Bellamy Transcript 16 November 2022 pp19-20 INQY1000263

[“CDSC”], and the Republic of Ireland, and was chaired by Dr Hannah Cohen, the British Society for Haematology representative.”<sup>247</sup>

Initially there was a “dual reporting route” where suspected infections were reported initially to the local blood centre, and from there suspected infections were reported to the PHLS. In England the reports were collated at the PHLS by an infection surveillance officer jointly funded by the blood service and the CDSC. In Scotland, reports were collated by the National Microbiological Reference Unit.<sup>248</sup> Reports of errors and immune complications were made directly to SHOT.<sup>249</sup>

The new system – a voluntary one – when launched in November 1996 was marked by an editorial in the *British Medical Journal: A SHOT in the arm for safer blood transfusion*.<sup>250</sup>

SHOT published its first report on 18 March 1998 covering 1996-97. 8 out of 169 reported serious hazards involved a viral or bacterial infection.<sup>251</sup> The English CMO, Sir Kenneth Calman, thought the report “raised the profile of blood safety amongst clinicians and the public”.<sup>252</sup> “Near miss” events were added as well as a “nil return” card in the second year.<sup>253</sup>

The account of SHOT’s development is a lesson in how to carry the support of a profession by gentle incremental growth. Reports from clinicians to SHOT were initially voluntary,<sup>254</sup> confidence was gained in the system, buttressed by experience that reports were indeed confidential, and more hospitals began to participate. It gained approval, such that from 2002 hospitals were required to participate in SHOT by the Department of Health.<sup>255</sup> SHOT has consistently had high levels of engagement: “Over the years, hospitals have ... had increasing confidence in SHOT which is reflected in the increasing number of reports. All but 2 UK NHS Trusts/Health Boards submitted reports during 2020; both of these are specialist centres and possibly low users of blood components.”<sup>256</sup>

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247 Written Statement of Dr Lorna Williamson para 247 WITN0643010

248 Written Statement of Dr Lorna Williamson para 243 WITN0643010. From November 2005 and the implementation of the Blood Safety (and Quality) Regulations 2005, a single reporting route was introduced with the Serious Adverse Blood Reactions and Events (“SABRE”) reporting system. This online reporting system was established by the Medicines and Healthcare products Regulatory Agency (“MHRA”) in conjunction with SHOT. Written Statement of Dr Lorna Williamson para 260 WITN0643010

249 For example, reactions between the donated blood and the patient eg transfusion-related acute lung injury or transfusion-associated graft-versus-host disease. Written Statement of Dr Lorna Williamson para 244 WITN0643010

250 Williamson et al *A SHOT in the arm for safer blood transfusion* British Medical Journal 16 November 1996 HSOC0004129

251 Letter from Kevin Woods to Colleague 2 February 1999 p4 SCGV0000039\_177

252 Letter from Sir Kenneth Calman to Pauline Banks 1 June 1998 p1 NHBT0015864\_001

253 Written Statement of Dr Lorna Williamson para 245, para 253 WITN0643010

254 Written Statement of Professor Michael Murphy para 176 WITN7001001, SHOT Annual Report 1996-1997 p8 NHBT0057437\_001

255 Department of Health *Health Service Circular 2002/009* 4 July 2002 p4 NHBT0062177\_001

256 Written Statement of Professor Michael Murphy para 181 WITN7001001, Extract from SHOT Annual Report 2020 WITN7001037

SHOT reports are sent to the four UK blood services as well as the departments of health in England, Wales, Scotland and Northern Ireland, professional bodies and reporting hospitals.<sup>257</sup> Its annual reports are published online<sup>258</sup> and contain recommendations for transfusion safety.<sup>259</sup>

Surveys are undertaken at the end of each year to find out whether measures recommended by SHOT have been implemented. Professor Bellamy, the present SHOT Steering Group chair, describes the extent to which measures are implemented as well as the response rates to the surveys as “*variable*”.<sup>260</sup> SHOT holds educational meetings upon publication of its annual reports as well as educational resources, known as “*SHOT bites*”.<sup>261</sup>

The latest SHOT annual report recorded 2 transfusion-transmitted infections for 2022. Both were Hepatitis B infections, the second identified through a lookback investigation. Between 1996 and 2022 SHOT recorded 43 confirmed transfusion-transmitted infections involving 35 donors. Of these infections, 15 were Hepatitis B (and 15 were Hepatitis E before screening was introduced).<sup>262</sup> Additional testing for Hepatitis B infections was agreed in 2021.<sup>263</sup>

Looking to the future, the desire of NHSBT is to set up a system where all outcomes of all transfusions are known rather than a system of reporting adverse events. This form of system “*has never been set up in this country and is very uncommon worldwide*” and would require new technology systems linking datasets. Funding has been agreed to see how this system could be established.<sup>264</sup>

It is clear that SHOT has been an effective initiative at reducing patient harm from blood transfusions. It has become a model for the basis of haemovigilance in other countries.<sup>265</sup> Prior to SHOT there was no national reporting system for transfusion risks. The question that naturally follows is why wasn’t SHOT – or a system like it – established earlier? One explanation offered is the “*disparate nature of transfusion services*” and a lack of organisational cohesion. Another is technology: “*there were no computers, everything was on bits of paper.*” However, as explained by Dr Williamson in her oral evidence to the Inquiry, none of these explanations “*were absolute show stoppers. They would have made the mechanics of doing it more difficult but I can’t see any reason, fundamentally, why there wouldn’t have been such a reporting system. But I never managed to find any record of one even having been discussed in the 1980s.*”<sup>266</sup>

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257 Written Statement of Professor Michael Murphy para 177 WITN7001001

258 The reports for every year since 1996 are available to download online at [www.shotuk.org](http://www.shotuk.org). The data is reported on an anonymous basis.

259 Professor Mark Bellamy Transcript 16 November 2022 p27 INQY1000263

260 Professor Mark Bellamy Transcript 16 November 2022 p27 INQY1000263

261 Written Statement of Dr Gail Mifflin para 1486 WITN0672006

262 SHOT Annual Report 2022 pp194-195 RLIT0002272

263 Professor James Neuberger Transcript 16 November 2022 p195 INQY1000263. Professor Neuberger is the chair of SaBTO. Written Statement of Professor James Neuberger para 2.8 WITN7306001

264 Written Statement of Dr Gail Mifflin para 1462 WITN0672006. She noted that the Scandinavian Donation and Transfusion database is an example of this sort of system.

265 For example, Denmark. Written Statement of Dr Lorna Williamson para 267 WITN0643010

266 Dr Lorna Williamson Transcript 8 December 2021 pp150-151 INQY1000169

## Systematic Reviews Initiative

In 2001 Dr Brian McClelland of the SNBTS and Professor Murphy of NHSBT established the Systematic Reviews Initiative (“SRI”). The purpose of this, which initially started with a grant from the NHSBT charity and is now funded by the four blood services and based at NHSBT’s Oxford Blood Centre, was and is to develop an evidence base for transfusion medicine. More than 100 reviews have been carried out. It produces the Transfusion Evidence Library which contains the systematic reviews as well as randomised controlled trials on all aspects of transfusion medicine.<sup>267</sup> These databases are updated monthly and provide free access to evidence for “*many thousands of healthcare practitioners, policy makers and researchers around the world.*”<sup>268</sup> The most recent annual report for SRI activities, covering the period of October 2022 to October 2023, demonstrates that it has contributed to 20 international and national guidelines.<sup>269</sup>

## The Better Blood Transfusion initiative

In June 1998 Sir Kenneth Calman, the English CMO, described that there had been “*Several recent high profile Healthcare issues [which] have focused on the Blood Services, especially the safety and availability of blood.*” In particular, the emergence of vCJD had “*caused concern for patients and the public*” about the safety of blood.<sup>270</sup> Following the same theme, the UK CMOs together hosted a symposium at St Thomas’ Hospital, London on 6 July 1998 addressing how better blood transfusion might be encouraged and supported.<sup>271</sup> This was the origin of what came to be known as the Better Blood Transfusion initiative.

Transfusion experts, clinicians, NHS managers and health authority chief executives attended from across the UK.<sup>272</sup> The conference took place in the context of concerns about potential blood shortages, the risk of infection from blood borne virus as well as the transmission of vCJD. “*Good evidence*” had been produced that “*significant unnecessary blood transfusion*” could be avoided.<sup>273</sup>

Following the conference, a draft health services circular was produced. It made a series of recommendations that were “*very much a first step along the way to better*

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267 Including a database on stem cell transplantation.

268 Written Statement of Professor Michael Murphy para 74c WITN7001001

269 Report of SRI activities and impact for the year October 2022 through to October 2023 p1 RLIT0002271

270 Letter from Sir Kenneth Calman to Pauline Banks 1 June 1998 p1 NHBT0015864\_001. Professor Dame Marcela Contreras told the Inquiry that the initiative came from the blood services. Together with Scottish colleagues “*we went to the Department of Health and to the Chief Medical Officer and convinced him, with raw data, of our audits that we had done in blood transfusion, that now other consultants in other centres were doing, that there was inappropriate use of blood.*” Professor Dame Marcela Contreras Transcript 2 December 2021 p156 INQY1000165. See also Written Statement of Sir Kenneth Calman paras 92.1-92.3 WITN3430001

271 Letter from Sir Kenneth Calman to Pauline Banks 1 June 1998 NHBT0015864\_001

272 NHS *Health Service Circular 1998/999* 11 December 1998 pp2-3 NHBT0083701\_002, Letter from Sir Kenneth Calman to Dr Robinson 22 June 1998 WITN3430096, Evidence Based Blood Transfusion Agenda 6 July 1998 DHSC0004467\_008

273 Letter from Sir Kenneth Calman to Pauline Banks 1 June 1998 p1 NHBT0015864\_001



*blood transfusion.*<sup>274</sup> The circular was finalised and published on 11 December 1998. It recommended a minimum course of action. From March 1999, the following action was required for all NHS Trusts where blood was transfused:

- to ensure that hospital transfusion committees are in place to oversee all aspects of blood transfusion.
- to participate in the annual SHOT enquiry.<sup>275</sup>

By March 2000 the following action was required for all NHS Trusts where blood was transfused:

- to have agreed and disseminated local protocols for blood transfusion, based on guidelines and best national practice and supported by in house training.
- to have explored the feasibility of autologous blood transfusion and ensured that where appropriate, patients are aware of this option. In particular they should have considered the introduction of perioperative cell salvage.<sup>276</sup>

The circular recognised that many NHS Trusts had introduced some or all of these recommendations but the Chief Medical Officers advised that “*all [NHS Trusts] should review their transfusion practice to ensure a safe, efficient and effective service for patients who need blood.*”<sup>277</sup>

In Scotland a management executive letter was circulated on 2 February 1999 setting out the same action points required of NHS Trusts to improve transfusion practice and Wales also issued the same guidance.<sup>278</sup> The circular issued by the CMO in Northern Ireland did not include the requirement to explore the feasibility of autologous blood transfusion, in particular red cell salvage.<sup>279</sup> In January 2001 *Better Use of Blood in Northern Ireland* guidelines were issued.<sup>280</sup>

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274 Memo from Dr Mike McGovern to CMO and others 14 August 1998 p1 WITN3430097

275 NHS *Health Service Circular 1998/999* 11 December 1998 p2 NHBT0083701\_002. Participation in SHOT had been voluntary before this. The policy aimed to grow compliance organically, by building up confidence in how best to avoid hazards of transfusion by reporting adverse reactions, rather than imposing it and having to struggle with the resentments that might bring since inevitably practices which had developed over time, and with which clinicians were comfortable, would be challenged in the process. Having developed a degree of “buy in” by these voluntary means, the circular now was able to mandate it and more effectively secure compliance. Written Statement of Dr Lorna Williamson paras 250-251 WITN0643010

276 NHS *Health Service Circular 1998/999* 11 December 1998 p2 NHBT0083701\_002

277 NHS *Health Service Circular 1998/999* 11 December 1998 p3 NHBT0083701\_002. Emphasis in original.

278 Letter from Kevin Woods to Colleague 2 February 1999 p2 SCGV0000039\_177, Letter from D Jones to Colleague pp1-2 HSSG0000132\_040

279 Letter from Dr Henrietta Campbell to Chief Executives of HSS Boards and others 8 March 1999 pp3-4 DHNI0000013\_016

280 The guidelines explained that there was a “*large variation*” in transfusion of red cells. “*To give one example, your chance, as a patient, of being transfused with red cells for primary total hip replacement varies from 30-100% depending on who carries out the operation. Differences cannot be accounted for by case mix, surgical technique or anaesthetic practices. The differences appear to be surgical team specific. Also poor documentation of red cell transfusions (no greater than 1/3 for post operative*

A second Better Blood Transfusion conference took place in October 2001. It was jointly organised by the National Audit Office, the National Blood Service and the Department of Health and chaired by the four UK CMOs.<sup>281</sup>

Prior to the conference Professor Murphy led a survey of NHS Trusts in England to determine the progress made in blood transfusion practice since the first conference.<sup>282</sup> The survey demonstrated that in some areas of blood transfusion practice very good progress had been made. These steps were the establishment of HTCs and participation in SHOT. However, more needed to be done in the multidisciplinary training of staff in blood transfusion, the availability of hospital transfusion practitioners, approval of local protocols based on national guidelines, auditing of blood transfusion practice, the use of autologous blood transfusion and the provision of written information to patients on blood transfusion.<sup>283</sup>

The aim of the four CMOs for the conference was “*a new ... up-front partnership between the UK NHS blood services and the public ... based on the recognition that the safety of blood cannot be guaranteed and that ... avoiding transfusion wherever possible must be an aim of clinical care ... embedded within and not peripheral to top level NHS management ... The plain message ... [was] we’ve come a long way since 1998 and we now need to set out the future.*”<sup>284</sup>

In England, a second circular was produced by the Department of Health on 4 July 2002. This included advice for hospitals on how to implement best transfusion practice.<sup>285</sup> Alongside a

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*transfusions) appears to reflect uncertainty in the minds of prescribing clinicians.”* Better use of blood in Northern Ireland: Guidelines for Blood Transfusion Practice January 2001 p9 DHNI0000013\_065

281 Written Statement of Professor Michael Murphy para 66 WITN7001001

282 Murphy et al *Survey of the implementation of the recommendations in the Health Services Circular 1998/224 ‘Better Blood Transfusion’* Transfusion Medicine 2003 DHSC0004261\_012

283 Written Statement of Professor Michael Murphy paras 69-70 WITN7001001. A similar survey was done in Northern Ireland. Letter from Jacqui Henry to Northern Ireland Advisory Committee board members 24 September 2002 p6 BHCT0000143

284 Memo from Dr McGovern to Mac Armstrong and others 2 July 2001 pp1-2 DHSC0038500\_049

285 Department of Health *Health Service Circular 2002/009* 4 July 2002 NHBT0062177\_001. Key actions were to:

- secure appropriate arrangements for Better Blood Transfusion and the appropriate use of blood;
- ensure senior management and Board level commitment;
- secure appropriate membership and functioning of the Hospital Transfusion Committee;
- secure appropriate composition and functioning of a Hospital Transfusion Team including support staffing and resourcing;
- ensure that appropriate blood transfusion policies are in place, implemented and monitored;
- ensure that education and documented annual training on blood transfusion policies are administered to all health care staff involved in the process of blood transfusion and is included in the induction and orientation programmes for new staff;
- improve the quality of service provision through clinical audit and continuing professional development;
- review the blood transfusion content of clinical multi-disciplinary audit and CPD programmes for NHS Trust staff, including the Hospital Transfusion Team;
- ensure that information for the traceability of blood is recorded and retrievable;
- ensure that information is available for monitoring the safety and appropriate use of blood;
- ensure that reporting of serious adverse events related to blood transfusion and near misses is being undertaken;

national comparative audit, the National Blood Transfusion Committee produced an online toolkit in 2003 for NHS Trusts to implement the Better Blood Transfusion initiative. National guidance, examples of good practice and patient leaflets were available online at this single website.<sup>286</sup>

The CMO's National Blood Transfusion Committee was established for England and North Wales to "*encourage good local blood transfusion practice and the implementation of national transfusion guidelines*".<sup>287</sup> In Northern Ireland there was an Advisory Committee on Blood Safety.<sup>288</sup>

The Scottish Government set up the NHS Scotland Better Blood Transfusion Programme in 2003 to reduce risks to patients from blood transfusion, "*mainly by reducing unnecessary, inappropriate transfusion*".<sup>289</sup> In Wales, a Blood Policy Group was created in 2005 to replace the initial forum which had "*encountered difficulties in exerting real influence on the NHS*".<sup>290</sup>

In September 2006, NHS Scotland published clinical standards on blood transfusion. These included:

- "*The NHS board has a system in place to ensure that every unit of blood component received into the hospital transfusion laboratory can be unmistakably traced to its recipient, or to its final fate if not transfused.*"
- "*The decision to transfuse is made following consideration of the potential risks and benefits of, and the alternatives to, transfusion. Where possible this is discussed between the clinician and patient (or their legal guardian) in advance of transfusion.*"
- "*Procedures are in place to optimise blood use and minimise wastage.*"<sup>291</sup>

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- ensure the appropriate use of blood and use of effective alternatives in clinical practice;
  - implement existing national guidance on the appropriate use of blood and alternatives;
  - ensure patients at risk of transfusion are informed of their choices;
  - ensure that timely written information is made available to patients on blood transfusion and alternatives;
  - promote the safe and appropriate use of blood and cost-effective alternatives in Trusts;
  - ensure that services commissioned are safe and value for money in relation to Better Blood Transfusion;
  - ensure that services for Better Blood Transfusion being provided are operating effectively and are part of local performance management arrangements.

Written Statement of Professor Michael Murphy para 71 WITN7001001. An updated circular was also issued in Northern Ireland. Letter from Dr Henrietta Campbell to Chief Executives of HSS Boards and Trusts and others 5 March 2003 BHCT0004020

286 Department of Health *Health Service Circular 2007/001* November 2007 p2 WITN7001011

287 The CMO's National Blood Transfusion Committee and Regional Transfusion Committees Terms of Reference June 2003 p1 DHSC0006783\_002

288 Dr Morris McClelland Transcript 1 February 2022 p139 INQY1000179

289 Written Statement of Professor Marc Turner para 403 WITN3530007

290 Welsh Health Circular WHC(2005)063 *New Blood Advisory Structure for Wales* 12 July 2005 p2 HSSG0000065

291 NHS Quality Improvement Scotland *Blood Transfusion Clinical Standards* September 2006 p15, p18, p22 RCSE0000004

In England, the Department of Health continued with the model of a conference followed by an updated Better Blood Transfusion circular, with the next produced in 2007 after a conference held on 16 March 2007. The Department of Health estimated that there had been a 15% reduction of red cell use in surgery following the first two circulars.<sup>292</sup> Progress had also been made in relation to HTCs, transfusion practitioners, the number of staff who had received transfusion training, the development of protocols for the use of blood, transfusion audit activity, clinical pathology accreditation of hospital transfusion laboratories and the number of NHS Trusts indicating that patient information is provided to patients attending pre-assessment clinics. However, further progress was noted to be required for the training of staff, the development of hospital transfusion teams, the development of protocols for the appropriate use of blood, the provision of information to patients and intra-operative cell salvage.<sup>293</sup>

The 2007 circular set out a Better Blood Transfusion Action Plan, with progress expected in all areas by November 2008 when the first audit of compliance was to be undertaken. Annual audits were planned up to 2012.<sup>294</sup>

On 18 June 2012 a further seminar took place: *Patient Blood Management – The Future of Blood Transfusion*. The National Blood Transfusion Committee published initial recommendations about how the NHS should implement the Patient Blood Management initiative. The initiative was described as “an evidence-based, multidisciplinary approach to optimising the care of patients who might need transfusion.” It was patient-focused and aimed at ensuring that patients received the best treatment and that “avoidable, inappropriate use of blood and blood components is reduced.”<sup>295</sup> It encouraged the use of alternatives to blood transfusion such as cell salvage, optimisation of blood counts and the use of drugs such as tranexamic acid.<sup>296</sup> Previous Better Blood Transfusion initiatives were noted to be successful leading to a reduction of red cell usage by over 20% over the previous ten years.<sup>297</sup>

A fifth, and the most recent, seminar was held in March 2019. It led to the Transfusion 2024 plan, a five year plan (from 2019) which outlined key priorities for clinical and laboratory transfusion practice for safe patient care across the NHS. Though acknowledging that “Over the last 10 years there has been considerable improvement in transfusion practice supported by evidence from clinical trials, implementation of guidelines and process improvements that have resulted in an overall reduction in blood use and significant cost savings for the NHS”, it noted that: “However, there is evidence of ongoing variability in transfusion practice within and between hospitals that may impact on patient outcomes needing further

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292 Memo from Dr Denise O’Shaughnessy to Robert Parsons and Ian Bishop 31 October 2007 p2 DHSC0004109\_006

293 Department of Health *Health Service Circular 2007/001* November 2007 p13 WITN7001011

294 Department of Health *Health Service Circular 2007/001* November 2007 pp3-12 WITN7001011

295 NHS National Blood Transfusion Committee *Patient Blood Management* 26 June 2014 p2 WITN7001027

296 Written Statement of Professor Michael Murphy para 135 WITN7001001

297 As at 2014. NHS National Blood Transfusion Committee *Patient Blood Management* 26 June 2014 p3 WITN7001027

action.” Accordingly, it makes a number of recommendations in relation to patient blood management, laboratory safety, IT and further research and development.<sup>298</sup>

In Northern Ireland, updated *Better Use of Blood in Northern Ireland* guidelines had been issued in 2009. The guidelines noted the findings of an audit in Northern Ireland which had found that 80% of patients transfused were admitted to hospital with anaemia, a significant number of whom could have been treated by other means; 19% of patients transfused were judged to have had an unnecessary transfusion; and some 29% of patients were overtransfused.<sup>299</sup> The Northern Ireland CMO issued an updated circular in 2011.<sup>300</sup>

In 2017 the NHS Wales Blood Health Plan was established following an all-Wales Welsh Blood Service being introduced as from 2016. Its ambition was that: “*The plan will not focus on the donation of blood or the production of blood components but will centre on good blood health and the use of blood components ... For people who need blood components we must value them as individuals, recognise transfusion is not without risk, agreeing with them treatment which only does what is necessary and does no harm.*”<sup>301</sup>

Broadly, the Better Blood Transfusion initiative was an effective approach and increased the safety of blood transfusions throughout the UK. Transfusion-transmitted infections are now rare events.<sup>302</sup> Despite the fact that transfused blood in all parts of the UK is considered to be safe, witnesses have concerns about whether compliance with best practice standards could be better, and believe that it should be. For example, the implementation of electronic transfusion systems in the UK has been “*patchy*”.<sup>303</sup>

### Advisory Committee on the Safety of Blood, Tissues and Organs

In 2008 the Advisory Committee on the Safety of Blood, Tissue and Organs (“SaBTO”) was created to provide independent advice on the safety of blood, cells, tissues and organs from transfusion/transplantation to all UK health ministers and health departments.<sup>304</sup> It

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298 Allard et al *Transfusion 2024: A 5-year plan for clinical and laboratory transfusion in England* Transfusion Medicine 2021 p1 WITN7001031. Table 1 has a summary of Transfusion 2024 recommendations.

299 Guidelines and Audit Implementation Network *Better Use of Blood in Northern Ireland: Guidelines for Blood Transfusion Practice* March 2009 p9 WITN3449065, The Northern Ireland Regional Transfusion Committee *Regional Appropriateness of Blood Transfusion Audit: Summary Report* WITN3449064

300 Circular on Better Blood Transfusion 3 Northern Ireland 24 August 2011 WITN7178008

301 Welsh Health Circular on NHS Wales Blood Health Plan 28 September 2017 p5 HSSG0000017. The Welsh Blood Service was created in 2009 but it was not until 2016 that management responsibility for the blood service in North Wales moved to the Welsh Blood Service. See the chapter on *Organisation of the Blood Services*.

302 See the chapter section on SHOT.

303 Professor James Neuberger, Professor Mark Bellamy and Dr Alison Cave Transcript 16 November 2022 pp153-159 INQY1000263, Written Statement of Professor James Neuberger paras 3.21-3.28 WITN7306001, Written Statement of Professor Mark Bellamy paras 39-40, 61-78 WITN7312001, Written Statement of Dr Alison Cave paras 8.8-9.9 WITN7477001, Written Statement of Professor Michael Murphy para 241 WITN7001001, Murphy et al *Electronic identification systems reduce the number of wrong components transfused* Transfusion 31 August 2019 WITN7001017

304 Written Statement of Professor James Neuberger p4 para 2.1 WITN7306001, Memo from William Connon to Elizabeth Woodeson and Baroness Dawn Primarolo December 2007 DHSC5498574



replaced MSBTO.<sup>305</sup> SHOT had been calling for such an overarching body since their 1998-99 report.<sup>306</sup> Its introduction meant that ministers received advice about **all** transfusion risks from the one committee.<sup>307</sup>

Dr Williamson describes that in contrast to the position in the 1990s, it is “*now much clearer that ... JPAC advises the Blood Services and that JPAC ... can be a resource on which SaBTO can call.*” Reflecting on the organisational changes, she concludes that “*the days of policy being set by any one individual in the transfusion landscape are firmly over.*”<sup>308</sup>

SaBTO has published guidelines about consent:

*“It is an accepted principle that a patient should give valid consent before receiving medical treatment, and this includes when they receive a transfusion of blood and blood components (such as fresh frozen plasma and platelets) ...*

*We recommend that:*

- *Informed and valid consent for transfusion is completed for all patients who will likely, or definitely, receive a transfusion ...*
- *Patients who have been given a blood transfusion and were not able to give informed and valid consent prior to the transfusion are informed of the transfusion prior to discharge and provided with relevant paper or electronic information.*
- *All patients who have received a transfusion have details of the transfusion (type[s] of component), together with any adverse events associated with the transfusion, included in their hospital discharge summary to ensure both the patient and their family doctor are aware.”*<sup>309</sup>

The Royal College of Physicians published a summary of these recommendations in their Concise Guidance series, which also supports the advice from the General Medical Council and other professional bodies regarding consent.<sup>310</sup> Among its key points are:

- *“The amount of information required to make consent truly informed may vary depending on the complexity and risks of treatment as well as the patient’s wishes.*
- *Consent should be obtained and documented for those who will or might receive (as evidenced by a sending of a specimen for ‘group and save’ or*

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305 By this time the MSBT had become the Advisory Committee on the Microbiological Safety of Blood Tissues and Organs (“MSBTO”).

306 The report concluded with a section “*Towards An Overarching View of Blood Safety in the UK*”. SHOT *Annual Report 1998-1999* 7 April 2000 pp89-92 NHBT0040229\_001

307 Written Statement of Dr Lorna Williamson para 266 WITN0643010

308 Written Statement of Dr Lorna Williamson para 753, para 755 WITN0643010

309 Guidelines from the expert advisory committee on the Safety of Blood, Tissues and Organs (SaBTO) on patient consent for blood transfusion 17 December 2020 p4 WITN7001044

310 Written Statement of Professor James Neuberger para 3.8 WITN7306001

*‘cross-match’) a transfusion of blood or components ... or being exposed to blood as in, for example ECMO [extracorporeal membrane oxygenation].*

- *Where transfusion may be required long term (eg, for those with sickle cell disease or undergoing chemotherapy), written consent needs be obtained only at the start of treatment and at 5-yearly intervals, although consent should be confirmed verbally before each transfusion.”<sup>311</sup>*

Another SaBTO initiative is developing principles for future lookback investigations.<sup>312</sup>

## Commentary

The system of blood transfusion is clearly safer now than it was, as a result of the initiatives described in this chapter. They are welcome. They have done much to improve a system in which – for too long and despite repeated advice – blood and blood components were given too readily, were frequently given in too great a quantity, with insufficient consideration of whether they were needed, and little or no consideration of alternatives which had less risk (not being biological products) such as tranexamic acid, pre-operative iron, or intra-operative cell salvage. Most importantly perhaps, little or no advantage was taken of the opportunity to discuss the desirability of transfusions, their risks and benefits, and any alternatives (including no transfusion) with patients. Though plainly in emergency circumstances this may not be practicable, this should have happened in almost all other cases.<sup>313</sup>

At the heart of the system, despite the very considerable improvements so far, remains a problem which will never entirely disappear so long as there remains no synthetic substitute for blood. Blood will never be pure in the sense that a chemical can be; so there is always the possibility of an unknown virus or other microbiological contaminant being transmitted, with the blood, to an unknowing recipient. Though the first few instances of this happening in the case of any previously unknown contaminant may be unavoidable (even if not unpredictable, for this is a “known unknown”) a careful system of haemovigilance and horizon scanning may help to identify the threat at an early stage, so that consideration can then be given as to how best to respond to it for safety’s sake.

When dealing with threats to safety, it has always been the case that the earlier an alert can be raised, the better. The “canary in the coal mine”; the telltale trickle from the wall of the dyke; the telltale crack in the glass of a masonry building; the recording of the near-miss event in aviation are all examples of applying the same principle. The Yellow Card scheme for licensed pharmaceuticals is another example. It too had been relied on for years

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311 Murphy et al *Consent for blood transfusion: summary of recommendations from the Advisory Committee for the Safety of Blood, Tissues and Organs (SaBTO)* Clinical Medicine 2021 p3 WITN7001045

312 Letter from Professor Neuberger to Sir Brian Langstaff 18 November 2021 JPAC0000230

313 And in emergency cases it was, and remains, important that patients should be fully informed at an appropriate stage after transfusion, both of the fact that they had been transfused and of any risks of viral transmission in consequence of that transfusion.

before Dr Robinson realised that similar principles could apply to blood, which did not need to be licensed.

She deserves credit for then acting on that realisation, and creating, bit by bit, the SHOT system. It is not her fault that it could quite easily have been developed earlier. It should have been. Hepatitis outbreaks during the Second World War prompted a focus on blood safety; it was known from then on that though identification of the viruses concerned remained elusive, the effects of infection could be serious. Without fully appreciating the risks of a transfusion, some clinicians often prescribed transfusions too casually – or gave a unit or additional unit just to “top a patient up”. A system that reported on adverse reactions to transfusions would give a sound basis for persuading these clinicians that this was likely to be poor care, rather than good care. Dr Williamson did not regard the reasons for not having a system such as SHOT earlier (the ones she identified being the disparate nature of blood services, and their lack of cohesion; and a lack of computerisation) as compelling. She said: *“I can’t see any reason, fundamentally, why there wouldn’t have been such a reporting system.”*<sup>314</sup> Nor can I, and I would add that if a Yellow Card scheme worked reasonably well for pharmaceuticals and licensed blood products, the principle of reporting adverse reactions, leading to identifying potential risks to others so that they might be avoided or reduced, was already established in the context of administering medical treatments in the same way as it was in many areas of life. Some system for identifying risks earlier could, and should, have come sooner.<sup>315</sup>

It needs to be added that if the way in which the blood services were organised was indeed part of the explanation as to why a form of SHOT did not happen earlier this cannot be a justification for it being later than it should have been. The regional organisation of the service in England and Wales is considered in the chapter on *Organisation of the Blood Services*: it should have been run as a unitary service long before the early 1990s. It may be telling that it was not before the National Blood Authority was established that Dr Robinson advanced her suggestion: it may have been the fact that it was now truly a national body in practical terms as well as in name that contributed to her doing so and being able to get SHOT up and running.

The evidence revealed slightly different views about the desirability of reporting to SHOT now being legally mandated (it is already professionally mandated). Professor Bellamy thought it would help, because:

*“we know that there is a large level of underreporting ... It simply isn’t credible that years go by when no hospital has a near miss ... I think for near misses, there is*

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314 Dr Lorna Williamson Transcript 8 December 2021 pp150-151 INQY1000169

315 It is right to acknowledge that the development of SHOT was an achievement: the UK became one of the first countries to establish truly national haemovigilance. Serious Hazards of Transfusion Annual Report 2000-2001 9 April 2000 p17 SHOT0000016. This does not however invalidate a conclusion that it should have been introduced earlier than it was, especially given the fact that a broadly comparable scheme had existed for pharmaceuticals and blood products for a long time before Dr Robinson’s initiative, and Dr Williamson’s evidence that she could not think of a good reason why it did not happen sooner.

*a tendency not to report things. But if you want a system which is robust, which is going to stop the real harm from taking place, you're not going to do that by waiting until that real harm occurs. You need to recognise the patterns beforehand. You need to recognise the behaviours, the practices, the systems errors, which lead to those near misses because it's only if you get rid of all the near misses that you're going to stop the eventual actual event from happening.”*<sup>316</sup>

In his statement he explained that “reporting ... to the MHRA [Medicines and Healthcare products Regulatory Agency] is mandatory for actual serious adverse events and reactions, but reporting to SHOT, for example, near-misses, is ‘professionally mandated’ but not legally mandatory, but forms part of clinical governance arrangements for Trusts and Health Boards ... although SHOT and MHRA use an integrated reporting portal”.<sup>317</sup> He thought that mandating Trusts to have a designated person in place to report haemovigilance matters might be possible. If such a post were not mandated, he feared that what would then be an optional position could be an early victim of cuts.<sup>318</sup> Professor James Neuberger, on the same panel, was “very much in favour” of legally mandating reporting, and said that having someone statutorily responsible would be a “very useful start.”<sup>319</sup> Dr Alison Cave said that statutory regulations do require serious adverse events to be reported, and the definition is wide enough to include a near miss which is part of a serious event,<sup>320</sup> but recognised that the legal obligation to report did not necessarily extend to near misses beyond that. She was concerned to encourage a system-wide culture for reporting, and feared that having a single person appointed as responsible might take away from a sense of collective responsibility. Making reporting as easy as possible seemed to her to be a critical factor in making an impact.<sup>321</sup>

This leads to the comment that all three of Professor Bellamy, Professor Neuberger and Dr Cave thought more reporting should be encouraged; all agreed that near-misses should be identified (indeed, the reasoning articulated for this by Professor Bellamy is compelling), and differed only on whether the effect of mandating a “responsible person” to ensure proper haemovigilance reporting would be to incentivise others to think of reporting or lead to them thinking that it was someone else’s responsibility. Though I understand Dr Cave’s point, for my part I think that mandating trusts and health boards to have a responsible person in place, as a first step, together with a regularly audited professional requirement

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316 Professor Mark Bellamy Transcript 16 November 2022 pp64-65 INQY1000263

317 Written Statement of Professor Mark Bellamy para 33 WITN7312001. He said “*the existing regulations are a little bit too flimsy and nebulous, whereas what is laid out for the MHRA reporting scheme and the BSQR [Blood Safety and Quality Regulations] is absolutely clear.*” Professor Mark Bellamy Transcript 16 November 2022 pp65-66 INQY1000263

318 Professor Mark Bellamy Transcript 16 November 2022 p66-67 INQY1000263

319 Professor James Neuberger Transcript 16 November 2022 pp66-67 INQY1000263

320 The Blood Safety and Quality Regulations 2005. A serious adverse event means “*any untoward occurrence associated with the collection, testing, processing, storage and distribution of blood or blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity*”. The Blood Safety and Quality Regulations 2005 p3 RLIT0001543

321 Dr Alison Cave Transcript 16 November 2022 pp68-69 INQY1000263

on doctors who are responsible for giving transfusions to include in their report not only that a transfusion was given (recording the identifiers of the unit(s)) but stating why it was given would be more likely to underpin the importance of haemovigilance than water it down.

A central message since the start of the NHS has been that blood transfusions may be necessary to keep patients alive. They are a valuable form of treatment. However, they should only be given where the benefits of doing so outbalance the risks. One of the lessons of this chapter is that clinicians may become set in their ways (and give blood because, in broad terms, they consider it a potential benefit and that doing so will do no harm; or because in the case of a hard-pressed maternity unit it will free up a bed space by hastening a mother’s recovery), and that they may pass on their established practice to junior doctors who are learning the job.

Changing the habits of individual doctors is not easy. However, the message for doctors in training has consistently been to give less blood if that does not significantly prejudice treatment; and not to give any unless doing so is properly indicated. It has almost as consistently been ignored by a very large number.

The fact that the National Blood Transfusion Committee has demonstrated by audit that some 20-30% of transfusions in major specialisms are currently given outside the recommendations found in national guidance shows that there is yet work to be done, despite a considerable reduction in the use of red blood cells over the last 25 years.<sup>322</sup> It also implies that before 2000, when the NBTC began work, a higher percentage still would not reach modern standards. Since the essence of these standards is not breathtakingly new – standards have for over 70 years stressed the avoidance of unnecessary transfusions – and since it has increasingly been shown by evidence that haemoglobin levels have historically been set at a higher level than actually needed,<sup>323</sup> it is obvious that too many clinicians gave too much blood by transfusion when it was unnecessary.

The CMOs should earlier have added their weight in a “Dear Doctor” letter advising doctors to be sparse in their use of transfusions of red blood, and where possible to take advantage of alternatives. The Department of Health and Social Care has suggested<sup>324</sup> that these matters were treatment decisions to be made by individual clinicians and that they were not matters to be dictated or instructed by the CMO. That misunderstands the point. Drawing attention to and emphasising the importance of avoiding the overuse of transfusion; highlighting the importance of clinicians considering alternatives or providing guidance as to the range of alternatives to consider; encouraging “better blood transfusion” – none of these amount to dictating or instructing individual clinicians, or interfering with “clinical freedom”.

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322 Written Statement of Professor Michael Murphy para 114 WITN7001001, Written Statement of Dr Jonathan Wallis para 158 WITN6982001

323 Especially in obstetrics.

324 In response to criticisms being put to the Department of Health and Social Care under the Inquiry Rules 2006.



Greater emphasis on team working amongst doctors, the greater integration of transfusion committees into practice, and the greater willingness of doctors to adopt evidence-based medicine, and an increasing value placed on patient autonomy have reduced the extent to which clinicians feel inclined to exercise “clinical freedom” in their transfusion practice.

The theme which runs through this chapter is that the words used in the first paragraph of this commentary deserve repetition: “for too long and despite repeated advice – blood and blood components were given too readily, were frequently given in too great a quantity, with insufficient consideration of whether they were needed, and little or no consideration of alternatives which had less risk.” Could this have been remedied earlier? If so, for the reasons Professor Dame Marcela Contreras gave, it is likely that infections would have been avoided, even though it may be difficult to know how many.

Even at the time of the Better Blood Transfusion initiative – and to some extent continuing today – changing the practice of clinicians who have habitually over and unnecessarily transfused their patients was not and is not an easy task. The medical professions have been too slow in applying a well-established message. The growth of audit in clinical practice enabled compelling evidence to be shown to many doctors, which unequivocally demonstrated how better to use blood, and its components. Ultimately, the problem has been substantially eased (though not yet entirely eliminated, it seems) by the development of HTC’s, leading to the Better Blood Transfusion initiative with its beneficial effects in all four nations of the UK. They were first proposed in 1984. Some other countries had adopted similar processes by 1989 when Dr Contreras called for their introduction across the UK. They could have begun earlier than they did (increasingly during the 1990s, but still only gradually), and it is reasonable to think would have had a similar effect to the effect they progressively had during the 1990s – only, this effect would have come some four or five years earlier than happened.

I do not underestimate the difficulties. I acknowledge that the change in transfusion behaviour from what was actually taking place to that which had been recommended decades earlier, and ever since, would not be an easy one, given the demands of practice and the individual nature of many cases. Nonetheless, effective measures to ensure better compliance with those recommendations, of one sort or another, were clearly needed. Using a valuable resource carefully demanded no less. But more importantly still, so did the safety of patients. HTC’s were not necessarily the only way of achieving this change. But since they were the mechanism which eventually enabled progress to be made, it is appropriate to focus on whether they should have come sooner in the UK. The evidence is compelling that they should.

Whose responsibility is this delay? Not the blood services as a whole, given the lead that first Professor Contreras and later Dr Robinson took. Not the Royal Colleges, which educated a more parsimonious use of transfusion and explained why that was in the course of the education they mandated. Hospitals – here the regional health authorities – were slow in setting up HTC’s. The DHSS and Department of Health, together with the Scottish Office, Welsh Office and the Northern Ireland Office, could have encouraged the process more

and earlier than they did, but the failure lies in this case not so much with an organisation or with government but with the large number of doctors who were reluctant despite the guidance, despite the trend of evidence, and despite the views of transfusion consultants, to reassess their outdated practices. The failure here is truly to be laid at the door of the profession generally.

I hope that this Report will bring home to clinicians that individual practices of over-transfusing and failing adequately to consider alternatives have undoubtedly exposed more people to a risk of transfusion-transmitted infection than should have been the case. Some of these patients have developed chronic infection with Hepatitis C; others (only a few, but more than would otherwise have been the case) have been infected with HIV. Some have died. Not all would have done so if fewer transfusions had been given. The consequence of many doctors not listening, not sufficiently respecting standards and guidance, and adopting familiar practice without questioning it has in some cases caused serious harm to their patients.

This is, of its nature, a generalisation – it must be borne in mind, for instance, that a finding that 20-30% of transfusions are outside current national guidance also means that 70-80% are within. More doctors have complied than have not: the previous paragraph thus criticises a minority, and an apparently reducing one. But there is work for all to do in ensuring that good practice is more widely adopted both by them, and by their colleagues, and complacency should not be an option.

This chapter has looked at the downside of transfusions. It should be recognised that, in general, transfusions very rarely cause harm to patients nowadays. This chapter is about a system that has historically been less reliable than it is today. Nonetheless, there remains no place for complacency – the relative safety of the system as it is now is a reflection more of the success of vigilance than it is of a system that is so safe that it does not require any. In particular, a report of an adverse consequence of a transfusion will more often than not begin with the patient. The patient cannot know that what they complain about may have been caused by a transfusion if they do not know that they have had one, or if (in the case of infections which have a long latency period) they do not understand that there may be symptoms after a considerable while. NICE issued a Quality Standard which reads: “*People who may need or who have had a transfusion are given verbal and written information about blood transfusion.*”<sup>325</sup> This is important. An audit has shown a lack of compliance with giving both verbal and written information, such that national compliance is 26%. Only 64% of transfused patients had evidence of receiving one or the other.<sup>326</sup> This is no ground for thinking it sufficient that the system has improved this far. There is more to be done. It must follow that the substantial underreporting of actual and potential adverse events which Professor Bellamy, Professor Neuberger and Dr Cave identified as a continuing problem is

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325 NICE *Blood transfusion* 15 December 2016 p15 RLIT0002268

326 NHS Blood and Transplant *2021 National Comparative Audit of NICE Quality Standard QS138* February 2022 p12 WITN7001061

likely to be greatly improved upon if patients are actually informed about blood transfusion as they should be.

The central problem with the non-compliance identified by such figures is likely to be caused by clinicians failing to treat transfusion seriously enough. In short, the problem is complacency. It has the consequence that (on the audit figures) 36% of patients were not put in a position in which they could give valid consent. The evidence has led to NHSBT submitting that the Inquiry should recommend that patients receiving blood transfusions “*are properly consented in compliance with NICE, SaBTO and professional regulator guidelines.*”<sup>327</sup> Their aim is obviously right, and the inference that it does not happen at the present is justified.

Reliance on reporting adverse events, and attributing them to transfusion, where they may take a while to show themselves puts the emphasis on patients to be proactive in making such reports. NHSBT advocate the establishment of a framework for a system where all outcomes of all transfusions of blood components become known and recorded. Such a system would enable the blood services to be proactive in determining what the outcome has been, rather than just reactive to patients’ reports. The proposal seeks both to improve haemovigilance and inform transfusion practice. It is needed because, as NHSBT say:

*“The recording of, and access to, information concerning transfusion is currently difficult in the NHS. The lack of integration between various records is an important limitation which hampers patient access to information, and limits the ability of the blood service to undertake tracing, audit and root cause analysis. Thus, a framework within existing systems should be established for proper recording of outcomes for recipients of blood components.”*<sup>328</sup>

The proposal should be welcomed.<sup>329</sup>

In summary, this chapter has described how a system has changed for the better. It was one in which too much blood was given unnecessarily to patients. Responsibility for this failing rests generally with the profession. It was one in which the risks of transfusion were rarely discussed with patients. Responsibility for that again rests with the profession. Alternatives to transfusion were insufficiently used. Responsibility for that is a mixture of the profession generally, the Department of Health and Social Care which did not take action in response to Professor Roberts’ many letters,<sup>330</sup> and to a lesser extent the blood transfusion services for failing to alert the hospitals and consultants they served to the advantages of these alternatives. HTCs, leading to the Better Blood Transfusion initiative, should and could have come earlier than they did.

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327 Closing Submissions of NHSBT paras 17.21-17.28 SUBS0000062

328 Closing Submissions of NHSBT para 17.58 SUBS0000062

329 I return to it in the chapter on *Recommendations*.

330 Written Statement of Professor Ian Roberts para 2 WITN7310001

Although the risks of each individual transfusion viewed on its own were small, the system overall exposed too many patients to too great a level of risk. Looking out for potential risks, and applying haemovigilance, was late in coming. This delay is in part that of the DHSS/ Department of Health for not encouraging changes of practice earlier, but in larger part a general failing of the profession.

## Summary

- (a) Over many years blood was used unnecessarily, being wrongly seen by many clinicians to be little or no risk. There was an unacceptable level of complacency about the safety of blood.
- (b) The unnecessary use, and overuse, of blood was particularly problematic in the treatment of pregnant and postpartum women and in the undertaking of non-emergency surgery.
- (c) It took until 1998, and the creation of the Better Blood Transfusion initiative, for a UK-wide framework addressing best practice in transfusion to be established and a concerted effort to be made to reduce unnecessary blood transfusions. This, or something as effective, should have happened earlier and there is no good reason why it took so long for coordinated action to be taken.
- (d) Earlier action could and should have included the issue by CMOs of “Dear Doctor” letters or health circulars regarding both overuse of blood and the use of alternatives.
- (e) There were measures that could and should have been introduced earlier than they were: those that could have been introduced were audits of blood usage; the creation of maximum blood ordering schedules; and the engagement of specialist transfusion practitioners.
- (f) HTCs should have been established earlier than they were.
- (g) There was (and remains, particularly in regard to tranexamic acid) insufficient use of alternatives to transfusion: in particular iron supplements, tranexamic acid and red cell salvage.
- (h) SHOT, or a similar haemovigilance scheme, should have been established earlier, in the 1980s.

The measures outlined above would, if addressed earlier, have reduced the level of infection and (in all likelihood) have saved lives.

- (i) There was a widespread (and wrong) failure to warn patients of the risks of transfusion, and of alternatives, where they could reasonably have been warned, both so that they could give informed consent and so that they could be alert to, and take steps with regard to, the possible health consequences of the treatment.

- (j) Many transfusions (whether on an emergency basis or because of a serious long-term condition) were undoubtedly necessary, but even in such cases patients should have been given information about the risks of viral transmission so that they too could be alert to the possible consequences and take appropriate steps to mitigate those consequences.
- (k) In all cases transfusion could and should have been properly recorded in patients' medical notes.

**Final words**

Though safety and systems have much improved over time, compliance by clinicians and in particular the informed involvement of patients in their own treatment by transfusion still require further improvement. There is no reason for complacency.



## 5.2 Hepatitis C Surrogate Screening

This chapter examines how the question of using surrogate testing for NANBH, through testing ALT levels and/or for anti-HBc, was addressed in the UK in the 1980s, and considers whether such testing could and should have been introduced.

### Key dates

**April 1981** *New England Journal of Medicine* publishes TTV study results.

**June 1981** Dr Brian McClelland presents proposal for prospective study to the MRC Working Party and no decision is taken; the same day the MRC Blood Transfusion Research Committee agrees no need for surrogate screening for NANBH.

**August 1981** *Journal of the American Medical Association* publishes NIH study.

**January 1982** *The Lancet* publishes outcome of study in Australia with similar findings as TTV study.

**January 1983** no decision taken by working party on further study proposal from Dr Brian McClelland.

**September 1983** working party focuses on AIDS – no further discussion of prospective study of NANBH markers.

**July 1984** report produced on NANBH in the West of Scotland by Drs Dow and Follett.

**February 1986** FDA recommends introduction of both ALT and anti-HBc testing.

**November 1986** working party reconvenes for first time since 1983 and proposes to discuss a protocol for a multi-centre study.

**March 1987** SNBTS minutes record decision to introduce surrogate testing next year.

**July 1987** Letter in *The Lancet* from SNBTS suggesting that surrogate testing is “inescapable”.

**April 1988** DHSS grants funding for multi-centre study.

**May 1988** the Chiron Corporation identifies and clones Hepatitis C virus.

### People

**Professor John Cash**, SNBTS, medical and scientific director from 1988

**Dr Marcela Contreras** deputy director, North London Blood Transfusion Centre

**Dr Brian Dow** senior grade scientific officer, Glasgow and West of Scotland Blood Transfusion Service

**Dr John Forrester** senior medical officer, Scottish Home and Health Department

**Dr Jack Gillon** consultant physician, South East Scotland Blood Transfusion Service

**Dr Harold Gunson** director, NBTS and chair, Working Party on Transfusion-Associated Hepatitis

**Dr Brian McClelland** director, Edinburgh & SE Scotland regional blood transfusion service

### Abbreviations

**ALT** Alanine transaminase

**anti-HBc** Hepatitis B core antibody

**NIH** National Institutes of Health, US

**TTV** transfusion transmitted viruses

**FDA** Food and Drug Administration, US

## Introduction

By at least the end of the Second World War it was well known that hepatitis could be transmitted by blood transfusion. For Hepatitis B, this problem was addressed in the 1970s partly through the development of increasingly sensitive tests.<sup>331</sup> These enabled donations that were positive for the Hepatitis B virus to be identified and discarded. Similarly, Hepatitis A could be identified directly through a test. However, despite increasingly sensitive testing methods, cases of hepatitis following blood transfusion continued. As discussed in more detail in the chapter *Hepatitis Risks 1970 and After*, this led to a third form of hepatitis being recognised: non-A non-B Hepatitis (“NANBH”).

Despite extensive efforts from at least the mid 1970s onwards, the virus responsible for NANBH – which became known as Hepatitis C – was not identified until 1988. Even following that discovery, further time passed before a test to screen blood donations for the virus was available for routine use across the UK. Such a test was not in use until 1 September 1991.<sup>332</sup>

In the meantime, those involved in decision-making in blood services faced a critical question: what should be done to reduce the risk of NANBH being transmitted by blood transfusion?

Where cases were identified as NANBH then, by the late 1970s, it was recognised that they carried with them serious risks of long-term consequences.<sup>333</sup> It was known that these could not be ascribed simply to Hepatitis B infection, for screening for Hepatitis B virus (“HBV”) had become increasingly effective from the start of the 1970s (though still remained as a risk and researchers were alert to the need to exclude it).<sup>334</sup> NANBH infection was usually less severe in its acute phase than Hepatitis B, and less often caused the yellowing of the skin which signposted jaundice to any observer, but once it was recognised that it had the potential for long-term consequences<sup>335</sup> (as it was increasingly after 1975)<sup>336</sup> it became

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331 Testing was an important part of reducing its risks – but so too were donor selection, donor screening, keeping adequate records, and reporting and reacting to post-transfusion incidence of transmission. See the chapter on *Blood Services and Addressing Risk*.

332 See the chapter on *Hepatitis C Screening*.

333 See the chapter on *Hepatitis Risks 1970 and After*.

334 After 1975, the Hepatitis B virus was tested for by radioimmunoassay (“RIA”) techniques. Previously it had been by immunoelectro-osmopheresis (“IEOP”) which was less sensitive.

335 As it was by 1978/79, following Dr Eric Preston’s paper: Preston et al *Percutaneous Liver Biopsy and Chronic Liver Disease in Haemophiliacs* The Lancet 16 September 1978 PRSE0003622, Memo from Dr Diana Walford to Mr Harley 15 September 1980 p1 WITN0282008

336 *The Lancet* then added to the concerns being expressed about the long-term consequences of NANBH in a report in May 1979. It spoke of NANBH being related to a “*high frequency of persistent hepatic dysfunction*”. Dienstag et al *Non-A Non-B Hepatitis Associated With Chronic Liver Disease in a Haemodialysis Unit* The Lancet 5 May 1979 p2 PRSE0002202. In the “*Discussion*” part of the article it adds: “*More and more data point to this [NANBH] as the cause of a substantial proportion of cases of post-transfusion hepatitis negative for HBsAg*”, citing: Feinstone et al *Transfusion-Associated Hepatitis Not Due to Viral Hepatitis Type A or B* New England Journal of Medicine 10 April 1975 PRSE0000093, Dienstag et al *Non-A Non-B Hepatitis Post-Transfusion Hepatitis* The Lancet 12 March 1977 PRSE0002602. The article also refers “*to its role in the subsequent development of chronic liver disease*”, citing: Purcell et al *Non-A, Non-B Hepatitis* Yale Journal of Biology and Medicine 26 February 1976 PRSE0000381, Knodell et al *Development of Chronic Liver Disease after Acute Non-A, Non-B Post-Transfusion Hepatitis: Role of  $\gamma$ -globulin prophylaxis in its prevention* Gastroenterology 1977 RLIT0000226, Koretz et al *Post-transfusion hepatitis: The Role of Hepatitis*

clear that in a high proportion of cases it led to cirrhosis of the liver and an increased risk of liver cancer. Cases had, however, to be identified clinically, once tests showed that the symptoms were caused neither by Hepatitis A nor Hepatitis B. This clinical diagnosis tended to be one of exclusion: if liver function tests produced consistently elevated results and no other more obvious cause than a viral infection could be found, it was probably viral. There was no one laboratory test that could identify it.<sup>337</sup>

In the absence of a test that could detect the agent responsible for NANBH directly, and of any confidence that such a test could be found quickly, research focused on tests that might detect NANBH indirectly through the presence of “surrogate” markers. The main candidates were raised alanine transaminase (“ALT”) levels and Hepatitis B core antibody (“anti-HBc”).<sup>338</sup> In deciding whether to rely on such markers, the principal issues, as they were approached by those involved at the time, were: a) whether discarding blood donations with raised ALT levels and/or positive anti-HBc results – and deferring or excluding the relevant donors – would reduce the likelihood that transfusion recipients would be infected with NANBH; and b) whether the perceived drawbacks of introducing such screening justified the anticipated benefits.

This chapter considers how those issues were addressed in the UK. It begins in the late 1970s and ends in 1990, by which time it had been decided that surrogate testing of blood donations for NANBH would not be introduced. Insofar as it concerns decision-making (or the lack of it), this chapter focuses on the domestic picture. However, the debate around the introduction of surrogate screening was heavily influenced by developments internationally. These included, in particular, the publication of two highly significant US studies on the potential value of NANBH surrogate screening in 1981 and, in 1986, a decision by the US Food and Drug Administration (“FDA”) to recommend the introduction of such screening. Those international developments are an important part of this chapter. More of those later: first, though, to the UK in the late 1970s when the potential seriousness of NANBH was becoming ever clearer.

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*B Antibody Gastroenterology* 1976 RLIT0002201, Alter et al *Non-A/Non-B Hepatitis: A Review and Interim Report of an Ongoing Prospective Study* Viral Hepatitis 1978 RLIT0002203

337 This problem was worldwide. The significance of NANBH and the need for a test for it was underlined in *The British Medical Journal* for 10 January 1981, recognising in an article focussed on the Netherlands that (at that stage) some investigators had found that the likelihood of developing NANBH increased greatly when donor blood contained ALT activity exceeding 45 international units whereas other investigators could not confirm this, and observing that the authors’ own findings that 3.4% of a group of 380 recipients of voluntary blood donations had developed NANBH emphasised “*the need for practicable methods of detecting non-A, non-B antigen(s).*” Katchaki et al *Post-transfusion non-A, non-B hepatitis in the Netherlands* *British Medical Journal* 10 January 1981 p1 NHBT0000114\_027

338 Raised ALT levels would suggest an abnormality of liver function, which could indicate the presence of hepatitis. The anti-HBc screen allowed identification of whether someone had previously had Hepatitis B in the past, which was a “lifestyle marker”: past exposure to Hepatitis B suggested that it was more likely that a person had also been exposed to NANBH.

## The late 1970s: early consideration of surrogate screening

Discussion of surrogate testing took place mainly through advisory and working groups, beginning in the late 1970s. None had any executive power. As will be seen, a recurring topic before each of them throughout the 1980s was a desire to obtain more data before reaching any decision as to what action should be recommended to those who had the power to act.

The possible use of ALT screening as a means by which to improve the safety of donated blood was considered at the first meeting of the Reconvened Advisory Group on Testing for the Presence of Hepatitis B Surface Antigen and its Antibody (“the Advisory Group”, also called the Maycock Group), held on 7 December 1978. It was agreed that the matter required consideration but that *“too stringent a ruling to exclude donors on the basis of a single raised transaminase, which is a non-specific indicator of liver dysfunction, might lead to the rejection of an unacceptably high number of donors.”* The Advisory Group was opposed to the *“routine determination of transaminase levels”* but considered further investigation to be warranted and deferred further discussions to its next meeting when Dr Tom Cleghorn (director of the North London Blood Transfusion Centre), who had been measuring transaminase levels in donors at his centre, would be in attendance.<sup>339</sup>

The Advisory Group duly revisited this topic at its next meeting on 2 April 1979. Dr Cleghorn presented his findings. He reported that several categories of people had been found *“to have raised transaminases not associated with viral hepatitis. Some 3% of new donors would be excluded if the criterion of one raised transaminase was applied. In addition there would be a problem of responsibility to apparently healthy donors found to have raised transaminase(s).”*<sup>340</sup>

These three considerations – raised ALT levels having causes other than hepatitis; the effect of introducing surrogate screening on the blood supply; and the additional responsibilities towards donors that would accompany such screening – recurred in the debate on this issue over the next decade and more.

Following Dr Cleghorn’s presentation, the minutes record an apparently unambiguous conclusion: *“The Advisory Group agreed that no new policy on testing for transaminases needed to be adopted. These tests should not be used to screen blood donors.”*<sup>341</sup>

While the Advisory Group did not recommend the introduction of ALT testing for blood donors, discussion of the ways in which post-transfusion hepatitis might be studied and addressed

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339 Note of the Advisory Group on Testing for the Presence of Hepatitis B Surface Antigen and its Antibody meeting 7 December 1978 p5 DHSC0002191\_099. Members of this group included Dr Richard Lane, Dr John Cash, Dr David Dane and Professor Arie Zuckerman. The Advisory Group’s terms of reference included: *“To advise the Department on measures which should be introduced to offer greater safety to recipients of blood and blood products and to protect the interests of blood donors.”* Note of the Advisory Group on Testing for the Presence of Hepatitis B Surface Antigen and its Antibody meeting 7 December 1978 p2 DHSC0002191\_099

340 Minutes of Reconvened Advisory Group on Testing for the Presence of Hepatitis B Surface Antigen and its Antibody meeting 2 April 1979 p6 CBLA0000931

341 Minutes of Reconvened Advisory Group on Testing for the Presence of Hepatitis B Surface Antigen and its Antibody meeting 2 April 1979 p6 CBLA0000931

continued. The Medical Research Council’s (“MRC”) Blood Transfusion Research Committee set up a Working Party on Post-Transfusion Hepatitis. At its first meeting, on 14 February 1980, this Working Party<sup>342</sup> concluded that related issues required investigation. Amongst these were: “*The identification of donors and units of blood associated with possible cases of non-A, non-B hepatitis*” and “*Epidemiological surveys to assess the size of the problem in relation to blood transfusions.*”<sup>343</sup>

## The early 1980s: the TTV and NIH studies

A highly significant development in the debate around surrogate screening for NANBH came with the publication of two US studies in 1981.

### The TTV study and its impact

The first publication arrived in April 1981, when a major piece of research by the Transfusion Transmitted Viruses (“TTV”) study group was published in the *New England Journal of Medicine*.<sup>344</sup> This study had prospectively followed 1,513 transfusion recipients from 1974 to 1979. It found that the attack rate for NANBH was 10% and that the incidence of hepatitis was directly related to ALT levels in blood donors. The article described the data collected in the study as providing “*substantial evidence that the level of donor ALT is related to the occurrence of non-A, non-B hepatitis in transfusion recipients.*” It commented that the “*extent of the association is sufficient to raise the question of whether ALT screening of donors should be reconsidered*”, and concluded that ALT testing was “*a potentially useful method of screening donors to reduce the incidence of non-A, non-B hepatitis.*” The “*observations*” in the report were said to “*suggest that about 40 per cent of the cases of non-A, non-B post-transfusion hepatitis among recipients in this study could have been prevented by discarding units with an ALT level<sup>345</sup> in the upper 3 per cent of the distribution*”. Recognising that, if ALT screening were to be initiated nationwide, there would be fewer units of blood for transfusion than presently available, the authors observed that this “*will undoubtedly require improved efforts in recruiting donors*” to meet transfusion needs.

The article further noted that the benefits of introducing ALT screening had to be “*carefully weighed against the number of potential donors that would be excluded, the overall*

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342 There had earlier been an MRC Working Party on Post-Transfusion Hepatitis which reported to the MRC Blood Transfusion Research Committee in 1974 (see below in text) but (somewhat confusingly) this body with a very similar title described the February 1980 meeting as its first.

343 Minutes of Blood Transfusion Research Committee Working Party on Post-Transfusion Hepatitis meeting 14 February 1980 p2 MRCO0000029\_003

344 Aach et al *Serum Alanine Aminotransferase of Donors in Relation to the Risk of Non-A, Non-B Hepatitis in Recipients* New England Journal of Medicine 23 April 1981 p2 PRSE0001650

345 Levels of ALT in the blood may fluctuate. The higher the level, the more likely it is that liver damage has been caused, since ALT is released in the course of the breakdown of liver cells. Later studies discussed in the text talk about “cut-off” points for screening, meaning levels above which a donation will not be acceptable, while one below that level will be. Aach et al *Serum Alanine Aminotransferase of Donors in Relation to the Risk of Non-A, Non-B Hepatitis in Recipients* New England Journal of Medicine 23 April 1981 p5 PRSE0001650



*incidence of hepatitis in recipients, and the severity of the disease.*<sup>346</sup> Other considerations would need to be taken into account, such as the time period for which a donor whose blood was rejected should be deferred, quality control of testing and advising donors on the implications of the ALT level. Notwithstanding these factors, the authors suggested that *“Although ALT screening lacks the sensitivity<sup>347</sup> to detect all infectious units and lacks the specificity to detect only infectious units, the high correlation between an elevated ALT level and infectivity of transfused blood provides a compelling argument that such screening should be instituted.”*<sup>348</sup>

Reference to the TTV study was soon made in the UK. Thus Dr Brian McClelland<sup>349</sup> offered to circulate a copy of the *New England Journal of Medicine* article at a 23 June 1981 meeting of Scottish National Blood Transfusion Service (“SNBTS”) directors. He also reported that he had prepared a protocol for a study of the transmission of NANBH by transfusion for an MRC meeting two days later.<sup>350</sup> Dr Brian McClelland duly presented this protocol at the 25 June 1981 meeting of the MRC’s Working Party on Post-Transfusion Hepatitis. This proposed a prospective study, to be undertaken in Edinburgh and Manchester, following 600 patients over a two-year period.<sup>351</sup>

The meeting minutes record that the protocol was based on a study recently completed in the US: ie the TTV study. As well as the desirability of obtaining accurate data on the

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346 In relation to severity of disease, the article suggested that approximately 20-40% of patients contracting NANBH were symptomatic, that at least 25% of all affected patients had aminotransaminase elevations lasting longer than six months, and that the development of chronic hepatitis and progression to cirrhosis had been observed.

347 “Sensitivity” is a measure of how far a test detects all the cases of infection in a sample; “specificity” is a measure of how accurately a test has identified nothing but cases of infection. To take an example – suppose that 10 of 100 patients are actually infected, a highly sensitive test will detect at least those 10, though it may detect more which would be “false positives”. A highly specific test would avoid detecting any cases where the patient was not infected – so it may, say, detect 5 of the 10: it will leave, in this example, 5 “false negatives”. The combination of the two, in sequence, should ideally result in the detection of all, or almost all, of the true cases of infection and no more.

348 A range of perspectives on this issue could be seen in the same edition of the *New England Journal of Medicine*. An editorial article by Dr Paul Holland and others, commenting on the TTV study group results, acknowledged that ALT screening of donors appeared to be a “*promising way to decrease the risk of post-transfusion hepatitis*”, while questioning whether the expected benefit to patients was “*worth the drawbacks, especially to the donors and to the blood-service complex*”. Holland et al *Post-Transfusion Viral Hepatitis and the TTVS* *New England Journal of Medicine* 23 April 1981 p2 PRSE0000257. The debate continued in a later edition, in which Dr Richard Aach highlighted that the TTV study group had not recommended that routine ALT screening be initiated immediately based on its findings, but pointed out that a serologic test was not yet available nor likely to be in the near future and that “*Until that time, screening of donor ALT might provide an interim means to reduce the incidence of non-A, non-B post-transfusion hepatitis*”. He noted that in both the TTV study and another by Dr Harvey Alter and others, “*the evidence was predictive rather than absolute – the same type of evidence that served as a basis for adoption of routine testing of donors for HBsAg in order to reduce Type B hepatitis transmission by transfusion*”. Aach *Letter to the Editor on Post-Transfusion Hepatitis and Serum Alanine Aminotransferase in Blood Donors* *New England Journal of Medicine* 13 August 1981 p2 PRSE0002572

349 Director, Edinburgh and South East Scotland Regional Blood Transfusion Service.

350 Minutes of SNBTS Directors meeting 23 June 1981 p5 PRSE0003924. The SNBTS directors agreed at the meeting that they would not proceed with liver function tests on existing donations for the time being.

351 Proposal for a Prospective Study of Post Transfusion Hepatitis in the UK 25 June 1981 PRSE0004584

incidence of transfusion-associated NANBH in the UK, one of the study's objectives was to obtain information as to whether ALT screening of donors might be of value in the UK.<sup>352</sup>

Dr Brian McClelland's proposal, however, faced resistance. Professor Arie Zuckerman stated that a study of post-transfusion hepatitis had already been undertaken in the early 1970s, in which 768 patients had been followed, and that the sera that had been collected remained available. The cost and administrative difficulties in carrying out a fresh study were raised, and it was said that a previous evaluation of ALT screening of donors at the North West Thames Regional Blood Transfusion Service had encountered difficulties in tracing donors found to have raised ALT values. The tenor of the Working Party's response to Dr Brian McClelland's proposal is reflected in the minutes. Universal ALT screening *"in the UK at the present time was agreed by the Working Party to be of doubtful value"*. Nonetheless, it was agreed that the chair – Dr Harold Gunson – would make enquiries to confirm whether the patient records and serum specimens from the earlier study were still available and that Dr Brian McClelland's project *"could then be reconsidered in the light of the specimens and clinical data available from the earlier study"*.<sup>353</sup>

The study to which Professor Zuckerman referred at this meeting had been carried out by the MRC Working Party on Post-Transfusion Hepatitis. Its results were published in a 1974 article in *The Journal of Hygiene*: *"Post-transfusion hepatitis in a London hospital: results of a two-year prospective study."*<sup>354</sup>

It is important to note that this 1974 study was based on data collected between July 1969 and December 1971. Accordingly, both the data collection and the article's February 1974 submission date for publication came before NANBH was widely recognised.<sup>355</sup> Indeed, the data collection pre-dated the availability of a developed test for Hepatitis B. It involved 768 patients and found an incidence of post-transfusion viral hepatitis of 1%. However, this excluded patients with raised ALT levels where potential causes other than hepatitis existed. The article explained that *"It was arbitrarily decided that where such other potential causes existed, the patient would not be regarded as suffering from viral hepatitis."*<sup>356</sup> It also acknowledged that the *"rigid exclusion of all patients having other possible causes*

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352 Minutes of Working Party on Post-Transfusion Hepatitis meeting 25 June 1981 p3 NHBT0000068\_049

353 Minutes of Working Party on Post-Transfusion Hepatitis meeting 25 June 1981 pp3-4 NHBT0000068\_049

354 MRC Working Party on Post-Transfusion Hepatitis *Post-transfusion hepatitis in a London hospital: results of a two-year prospective study* Journal of Hygiene (received 1974) PRSE0002988. The MRC Working Party minutes record Professor Zuckerman as stating that the MRC study involved three regions. The article suggests only one was involved but it seems clear that this is the MRC study he was referring to, not least because both the minutes and the article refer to the same number of patients.

355 This was reflected in its aims, which were: (a) to obtain information about the incidence of icteric (jaundiced) and anicteric (non-jaundiced) post-transfusion hepatitis; (b) to establish the frequency of Hepatitis B antigen and antibody in blood donors and patients and attempt to correlate their presence with blood transfusion and its complications; (c) to determine the frequency of transmission of Epstein-Barr virus and cytomegalovirus by blood transfusion and their role in causing post-transfusion liver damage.

356 MRC Working Party on Post-Transfusion Hepatitis *Post-transfusion hepatitis in a London hospital: results of a two-year prospective study* Journal of Hygiene (received 1974) p6 PRSE0002988

for their liver damage may have contributed to the low incidence of hepatitis in the present study".<sup>357</sup> These factors significantly limited the study's value as a guide to the likely incidence of NANBH.

As well as the scepticism displayed by Professor Zuckerman and others at the Working Party's meeting, further evidence of doubt as to the merits of surrogate screening was evident at a meeting of the wider MRC Blood Transfusion Research Committee, held in the afternoon of 25 June 1981.<sup>358</sup> In summarising the discussion of this issue by the Working Party, Dr Gunson explained that ALT levels were being "used in America to indicate liver damage but would reduce greatly the number of possible donors".<sup>359</sup> Although Dr (later Professor) John Cash expressed his support for a prospective study of ALT levels, it "was agreed that there was at present no need to screen potential blood donors for non-A non-B hepatitis".<sup>360</sup>

While the Working Party was not in favour of its introduction, despite the encouragement of it by the report of the TTV study group, the merits and drawbacks of NANBH surrogate screening had begun to be discussed in UK medical journals. They were the subject, for example, of an 11 July 1981 editorial in *The Lancet*.<sup>361</sup>

### The NIH study and continued debate

A second significant US publication of the early 1980s came on 7 August 1981. *The Journal of the American Medical Association* published the results of a study by a group at the National Institutes of Health ("NIH"), led by Dr Harvey Alter. This involved the prospective follow-up of 283 patients who were transfused following open-heart surgery. Hepatitis developed in 12.7% of patients, of which 97% was NANBH. ALT tests on 3,359 donors "indicated that risk of hepatitis was significantly<sup>362</sup> associated with the level of donor ALT".<sup>363</sup> Having noted the

357 MRC Working Party on Post-Transfusion Hepatitis *Post-transfusion hepatitis in a London hospital: results of a two-year prospective study* Journal of Hygiene (received 1974) p12 PRSE0002988

358 Minutes of Blood Transfusion Research Committee meeting 25 June 1981 pp2-3 CBLA0001396. The MRC Blood Transfusion Committee was disbanded in July 1982 on the basis that its work was being duplicated elsewhere. Letter from Helen Duke to Dr Lane regarding MRC Blood Transfusion Research Committee 19 July 1982 CBLA0001600

359 Minutes of Blood Transfusion Research Committee meeting 25 June 1981 pp2-3 CBLA0001396

360 A similar conclusion was reached in the *Third Report of the Advisory Group on Testing for the Presence of Hepatitis B Surface Antigen and its Antibody*, issued in 1981, albeit with a recommendation that the matter be kept under review. While recommending that research be undertaken to determine the extent and severity of post-transfusion NANBH, the report advised against introducing screening on the basis that some 3% of new donors would be excluded if the relevant criterion was one raised ALT level, that there would be a need for confirmatory testing and that the "worry and inconvenience caused to donors would be unlikely to be compensated for by any clinical benefit." *Third Report of the Advisory Group on Testing for the Presence of Hepatitis B Surface Antigen and Its Antibody* 1981 p10 PRSE0000862. The report was endorsed at an 11 May 1981 meeting of the DHSS Advisory Group on Hepatitis. Minutes of Advisory Group on Hepatitis meeting 11 May 1981 p5 DHSC0000128

361 *Screening of Blood Donors for Non-A Non-B Hepatitis* The Lancet 11 July 1981 PRSE0002719

362 In this context, this refers to the statistical probability of the finding of an association arising by chance, rather than by (say) cause and effect.

363 Alter et al *Donor Transaminase and Recipient Hepatitis: Impact on Blood Transfusion Services* Journal of the American Medical Association 7 August 1981 p1 PRSE0002216

recent publication of the TTV group results, the article described the NIH study as confirming “*the significant association of an elevated ALT level in donor blood and the development of recipient posttransfusion hepatitis; it suggests that pretransfusion screening of donor blood for ALT level can identify some carriers of the NANB [non-A non-B] hepatitis virus and possibly prevent approximately 30% of transfusion-related hepatitis*”. The authors explained that, as with the TTV study, “*our recipients were increasingly liable to have hepatitis develop the higher the ALT level of the donor and, conversely, the higher the donor ALT level, the more likely that donor was to be associated with a case of posttransfusion hepatitis*”.<sup>364</sup>

Drawbacks to ALT testing were highlighted by the NIH group: in particular, 70% of post-transfusion hepatitis would not be prevented by screening donors for ALT. In addition, 72% of the donors with elevated ALT levels in the study were not associated with a case of post-transfusion hepatitis and it was probable that many donors with elevated ALT levels were not in fact carriers of a hepatitis virus. The adoption of ALT screening would, “*at best, be an interim measure*” pending the discovery of a specific serological test for NANBH.<sup>365</sup>

Having noted that the NIH and TTV studies combined provided data on more than 8,000 donors and 1,500 recipients, the article further commented that together they raised “*many difficult ethical and practical issues*.” The paramount question, it was suggested, was whether the findings were sufficient to require the introduction of ALT screening, or whether a randomised, controlled prospective study was needed to confirm that the predicted reduction in post-transfusion hepatitis could actually be achieved. Parallels and differences with the introduction of Hepatitis B testing were set out, as well as the different interests and considerations involved in deciding whether to introduce ALT screening. The issue was described as a “*tenuous balance between risk and benefit*” and one that would require thought and planning.<sup>366</sup>

As well as the TTV and NIH studies, other international reports relevant to the potential introduction of NANBH surrogate screening appeared in the early 1980s. For example, on 23 January 1982 *The Lancet* published the outcome of a study by the Australian Red Cross that had followed 842 cardiac surgery patients in Sydney. Post-transfusion hepatitis was identified in 2% of patients, with 78% of this being cases of NANBH. The study found that a significantly higher proportion of the units of blood given to the patients who developed NANBH contained antibodies against both Hepatitis B core antigen and Hepatitis B surface antigen. Having noted the results of the TTV study in relation to ALT screening, the authors commented that: “*Our findings suggest that anti-HBc screening might have a similar effect of reducing by about half the number of cases of post-transfusion non-A, non-B hepatitis*”.<sup>367</sup>

364 Alter et al *Donor Transaminase and Recipient Hepatitis: Impact on Blood Transfusion Services* Journal of the American Medical Association 7 August 1981 pp1-4 PRSE0002216

365 Alter et al *Donor Transaminase and Recipient Hepatitis: Impact on Blood Transfusion Services* Journal of the American Medical Association 7 August 1981 pp1-4, p5 PRSE0002216

366 Alter et al *Donor Transaminase and Recipient Hepatitis: Impact on Blood Transfusion Services* Journal of the American Medical Association 7 August 1981 pp1-4, p5 PRSE0002216

367 The study was by: Cossart et al *Post-Transfusion Hepatitis in Australia* The Lancet 23 January 1982 p5 NHBT0000080\_004



Thus, by the start of 1982 careful studies of a large number of patients had concluded that a third or more NANBH infections would probably be excluded if either ALT testing or anti-HBc testing were introduced. But the studies were respectively of cases in the US and Australia, and their findings might not therefore apply with the same force in the UK. The initial proposal (in mid 1981) by Dr Brian McClelland that there should be a study in the UK had been made (and rejected) before either of these two later studies appeared to confirm what was at least an international perspective. Did it need now to be revisited in the light of these international developments?

## 1982-1983: UK consideration

On 27 September 1982, a UK Working Party on Transfusion-Associated Hepatitis met for the first time. It was agreed that Dr Brian McClelland would produce an outline study protocol for either “a) *determining the incidence of recipients with ‘transaminitis’ so that a library of putative non-A, non-B hepatitis samples could be collected ... or b) determining the incidence of PTH [post-transfusion hepatitis] in recipients of blood positive for existing putative markers of non-A, non-B hepatitis*”, which might include non-specific markers like ALT level and/or the presence of anti-HBc in donors.<sup>368</sup> The meeting also discussed the availability of existing samples for study. In light of sera from the US TTV study not being available for analysis in the UK, as appears to have been anticipated, Dr Gunson would ask the MRC if samples from the 1974 UK prospective study on transfusion-associated hepatitis could be made available.<sup>369</sup>

Dr Brian McClelland consequently produced a paper dated 10 January 1983 with an outline proposal for a prospective study of NANBH. This explained that two approaches had been considered. The first was a prospective study of a large number of transfusion recipients and their respective donors. Its objectives would include obtaining a measure of the incidence of post-transfusion NANBH. This approach, however, was discounted on the basis that a similar study had been undertaken in 1974 (ie the MRC study) and that samples from the MRC study were believed to be available for analysis, and because of likely cost and scale.<sup>370</sup> The second approach outlined in the paper was a prospective study “*to investigate the possible value of one or more putative markers of Non A Non B hepatitis in predicting the ability of a given blood donor to transmit the disease to a transfused recipient.*” The

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368 The minutes record that Dr Brian McClelland and Dr Howard Thomas preferred the second of these two types of study. Minutes of UK Working Party on Transfusion-Associated Hepatitis meeting 27 September 1982 pp2-3 CBLA0001625

369 Minutes of UK Working Party on Transfusion-Associated Hepatitis meeting 27 September 1982 p3 CBLA0001625. Dr Gunson subsequently made this request by letter dated 13 October 1982. Letter from Dr Gunson to Dr Barbara Rashbass regarding the Working Party on the former Blood Transfusion Research Committee 13 October 1982 NHBT0094562\_001. An initial response, dated 29 October 1982, from the MRC sought further information on the request, including where Dr Gunson believed the samples might be held. Letter from Dr Keith Gibson to Dr Gunson 29 October 1982 CBLA0001635

370 Dr Brian McClelland suggested that a multi-centre study of this type would cost £250,000 to £500,000 and commented that he was not in a position to prepare even an initial outline of a study on this scale without extra resources. Outline Proposal for Prospective Study of Non-A Non-B Hepatitis 10 January 1983 p1 CBLA0001666



markers would include ALT levels and anti-HBc.<sup>371</sup> This study would follow up recipients and donors and its estimated cost over 18 months was £63,000.<sup>372</sup>

When the Working Party met on 18 January 1983, it discussed a wider range of potential studies on transfusion-associated NANBH than had been outlined in Dr Brian McClelland's paper. It was agreed that "*some form of study was needed so that the U.K. is equipped [sic] to answer queries about any specific or non-specific tests for non-A, non-B offered from abroad*", though no decision was taken as to the type that should be carried out. Dr Brian McClelland circulated his proposal for a prospective study of NANBH and members were invited to provide him with comments.<sup>373</sup> The meeting also discussed the availability of stored samples. The MRC had not yet confirmed whether the samples from the 1974 MRC study were available and if the recipients involved had been followed up to look for long-term effects, and Dr Gunson agreed to contact them again.<sup>374</sup> It was agreed that, if the MRC samples were not available, the Working Party would put forward proposals for some form of study to the MRC and Department of Health and Social Security ("DHSS").<sup>375</sup>

Dr Gunson continued his attempt to obtain samples collected during the MRC study.<sup>376</sup> However, it soon became apparent that these efforts were in vain. In a 25 February 1983 letter, Dr Keith Gibson of the MRC informed Dr Gunson that many of the samples from the previous study had been lost as a result of power failures some time ago.<sup>377</sup> Professor

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371 The four proposed tests were: ALT value; Anti-HAV-IgM; Anti-HBc-IgM; and "*markers of putative Non A, Non B systems*". Outline Proposal for Prospective Study of Non-A Non-B Hepatitis 10 January 1983 p3 CBLA0001666

372 Outline Proposal for Prospective Study of Non-A Non-B Hepatitis 10 January 1983 pp4-5 CBLA0001666

373 Minutes of UK Working Party of Transfusion-Associated Hepatitis meeting 18 January 1983 pp2-3 NHBT0000023\_002

374 It was also noted that, if there had been "*no long term follow-up this should be built into any future study since the chronic liver damage risk of non-A, non-B hepatitis is one of the most important parameters requiring clarification.*" Minutes of UK Working Party of Transfusion-Associated Hepatitis meeting 18 January 1983 p3 NHBT0000023\_002. The minutes additionally record that Dr Brian McClelland would contact Newcastle to enquire about the availability of samples from their study. He did so in a 22 February 1983 letter to Dr James at the Freeman Hospital: Letter from Dr Brian McClelland to Dr James 22 February 1983 SBTS0000905. Dr James replied on 3 March 1983, expressing a willingness to collaborate with the Working Party while noting he and his colleagues wished to avoid defrosting and refreezing their stored sera on too many occasions: Letter from Dr James to Dr Brian McClelland 3 March 1983 BPLL0002337\_003

375 As for funding, the minutes suggest that Dr Brian McClelland would explore individual commercial funding for a pilot study in Edinburgh, and that Dr Gunson and Dr Lane would approach the Wellcome Fund informally for possible funding. Minutes of UK Working Party of Transfusion-Associated Hepatitis meeting 18 January 1983 p3 NHBT0000023\_002

376 In an 11 February 1983 letter to Dr Keith Gibson at the MRC, Dr Gunson commented that: "*Unless we are able to obtain data relating to the situation within the U.K. we may be placed in the position of taking up a test, for medico-legal considerations if nothing else, developed abroad where the incidence or characteristics of the illness differs from that in the U.K. Such a decision could cost the N.H.S. several millions of £'s each year.*" Letter from Dr Gunson to Dr Gibson 11 February 1983 p2 NHBT0094563

377 He added that an audit of what was left would be carried out but that this would take some weeks. Letter from Dr Gibson to Dr Gunson 25 February 1983 p1 PRSE0000781

Zuckerman subsequently informed Dr Gibson of his discovery that a complete duplicate set of samples had been disposed of when the unit where they were stored had closed.<sup>378</sup>

Dr Gunson shared this information at a 20 April 1983 meeting of the Working Party on Transfusion-Associated Hepatitis and it was acknowledged that this ruled out the chance of updating the testing of samples from that study with modern diagnostic assays.<sup>379</sup> It was noted during the meeting that no source of funding had been found to date for Dr Brian McClelland's proposed study.<sup>380</sup>

Dr Gunson later gave evidence in court that around 1983<sup>381</sup> he tried to secure a study of donor recipients, but failed. He said "*I was trying to generate it [data] and seemed to be blocked at every stage.*"<sup>382</sup>

A further meeting of the Working Party took place on 27 September 1983. Much of the discussion focused on AIDS. In the context of non-specific tests for AIDS, there was brief reference to anti-HBc, which was noted to have the value of association with Hepatitis B and NANBH as well as AIDS. There was no further discussion of a prospective study of NANBH markers.<sup>383</sup>

From around this time, attention appears to have been diverted away from NANBH. Dr Brian McClelland described the transfusion service as "*losing sight of*" NANBH for several years from 1983, when those involved were extremely preoccupied with HIV/AIDS.<sup>384</sup> The Working Party on Transfusion-Associated Hepatitis did not meet again until November 1986, more than three years after its previous meeting.<sup>385</sup>

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378 Professor Zuckerman described this as an "*absolute disaster*" in light of the effort that had gone into the collection of samples and follow-up of patients during "*this unique survey of post-transfusion hepatitis in Britain.*" Letter from Professor Zuckerman to Dr Gibson 13 April 1983 MRCO0000032\_005

379 Minutes of UK Working Party of Transfusion-Associated Hepatitis meeting 20 April 1983 pp1-2 NHBT0000023\_003. The meeting also discussed potential requests to Dr James of the Freeman Hospital for access to his samples. Dr James and colleagues had carried out a prospective study of 248 patients who had undergone cardiac surgery. The results of that study were published in *The British Medical Journal* on 12 November 1983, in terms suggesting that NANBH after blood transfusion "*from a largely British blood donor group probably leads to clinically significant chronic liver disease very rarely indeed.*" Collins et al *Prospective study of post-transfusion hepatitis after cardiac surgery in a British centre* *British Medical Journal* 12 November 1983 p3 PRSE0000766

380 The possibility of seeking funding from the MRC for a joint study involving Edinburgh and the North London Blood Transfusion Centre was also discussed and it was minuted that Dr John Barbara would speak to the director and submit a draft proposal. Minutes of UK Working Party of Transfusion-Associated Hepatitis meeting 20 April 1983 p3 NHBT0000023\_003. In his oral evidence to the Inquiry Dr Brian McClelland stated that he never saw a follow-up proposal from Dr Barbara in relation to this. Dr Brian McClelland Transcript 28 January 2022 pp96-7 INQY1000178

381 The attempt related to Dr Gunson's time when he was director of the Manchester Blood Transfusion Centre as well as consultant adviser to the Chief Medical Officer on matters of blood transfusion. See his cross-examination on 26 October 2000 in: *A v National Blood Authority* 26 October 2000 p87 NHBT0000148\_001

382 Court transcript of cross-examination of Dr Harold Gunson in: *A v National Blood Authority* 26 October 2000 p87 NHBT0000148\_001

383 Minutes of UK Working Party on Transfusion-Associated Hepatitis meeting 27 September 1983 p4 PRSE0001299

384 Dr Brian McClelland Transcript 28 January 2022 p97 INQY1000178

385 Minutes of UK Working Party of Transfusion-Associated Hepatitis meeting 24 November 1986 NHBT0000023\_007

## 1984-1985

A small number of developments in 1984-85 are of note. Though both the US studies had focussed upon the utility of ALT testing as a marker for NANBH, in December 1984 an article published in the *Annals of Internal Medicine* considered the role of anti-HBc as a surrogate. Using data from the TTV study, the authors found that units of blood that were positive for antibody to anti-HBc were associated with a twofold to threefold greater risk of NANBH in the recipients than units without anti-HBc. The results suggested that the incidence of NANBH might have been reduced by about one third through anti-HBc screening. However, it was also recorded that more units of blood would be discarded as a result of the use of anti-HBc than with ALT screening.<sup>386</sup>

During this period, work on NANBH was also undertaken in Scotland. In July 1984, Dr Brian Dow (of the Glasgow and West of Scotland BTS) and Dr Eddie Follett (of the Glasgow Regional Virus Laboratory) completed a report on NANBH in the West of Scotland. This concluded that NANBH was “*not a major problem*” in the region. It did so because in the previous four years only fourteen cases of non-A non-B post-transfusion hepatitis had been notified to the Glasgow and West of Scotland BTS, of which four “*were haemophiliacs who had been multiply transfused with Scottish and imported blood products*”. It went on: “*It would therefore appear that PTH [post-transfusion hepatitis] is not a significant problem in this region although sub-clinical forms of PTH probably occur but are not being notified.*”<sup>387</sup>

This finding is problematic. First, in drawing the conclusion that there was no significant problem it did not rely on any empirical or observational work. It relied on reports of NANBH infection being made (mostly by others), and also their attribution to transfusion. Only cases of “*infective jaundice*” had to be notified. That description suggests icteric hepatitis, indicated by a yellowing of the skin. Yet only a minority of cases of NANBH were associated with this. Moreover, cases of NANBH were clinically identified by two or more successive tests showing elevated liver transaminases where the case did not test positive for either the presence of Hepatitis A or B, and other identifiable causes could be excluded. These infections often proved most symptomatic in the chronic phase, some time after jaundice – if it existed at all – would have been apparent. In short, the link between NANBH and transfusion could be difficult to draw and significant under-reporting was almost inevitable. Indeed, Dr Dow himself wrote in 1987 that 99% of cases of post-transfusion NANBH were never reported to transfusion centres.<sup>388</sup>

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386 Stevens et al *Hepatitis B Virus Antibody in Blood Donors and the Occurrence of Non-A, Non-B Hepatitis in Transfusion Recipients* *Annals of Internal Medicine* December 1984 p1 PRSE0004356. For an example of an article highlighting the drawbacks of both ALT and anti-HBc screening, and proposing greater medical education and more restrained blood usage to minimise new post-transfusion NANBH cases, see: Wick et al *Non-A, non-B hepatitis associated with blood transfusion* *Transfusion* March-April 1985 PRSE0001600

387 The report also set out the results of ALT tests on 10,655 blood donors, including those from prison sessions, and noted that these results had “*discouraged the SNBTS from visiting prisons to obtain blood for transfusion purposes.*” *Non-A, non-B Hepatitis in the West of Scotland* July 1984 pp5-6 PRSE0002577

388 In a letter to *The Lancet* dated 13 June 1987, Dr Dow, Dr Follett and Dr Ruthven Mitchell noted that “*99% of hepatitis cases are never brought to the attention of transfusion centres or are not considered*”

This work did not provide sound evidence for reaching the conclusion expressed. Further, there was follow-up of some but not all of the donations tested.

Lord Penrose observed in respect of the report: *“In addition, reports of notifications of an infectious disease whose characteristics were poorly understood by clinicians generally were most unlikely to provide sound evidence of prevalence of the condition. Without follow-up of the donations tested, the study did not provide a basis on which the prevalence of post-transfusion NANB Hepatitis could, or should, have been drawn ... [The study did not] indicate the potential value of ALT surrogate testing, or a basis for assessing that value.”*<sup>389</sup> I agree.<sup>390</sup>

In October 1985, Dr Dow completed a PhD thesis on NANBH in West Scotland, building on the work he had undertaken with Dr Follett. This concluded that transfusion-associated NANBH in the West of Scotland was a very rare occurrence, with an average of only three reported cases annually.<sup>391</sup> Again, however, reliance was placed on cases having been reported as arising from a transfusion. The error in this conclusion is thus readily apparent. Given that most cases of NANBH were sub-clinical, relying only on reported cases to conclude that transfusion-associated NANBH was “*very rare*” was inevitably flawed. As this was a PhD thesis – rather than, for example, the work of an expert working group – one might not have expected the error to be of any significance in understanding decision-making on the introduction of surrogate screening in this period. However, as explained further below, Dr Dow’s conclusions were to feature heavily in the Scottish Home and Health Department (“SHHD”)’s consideration of surrogate screening in the years that followed.<sup>392</sup>

Finally, in relation to the period from 1984-85, there remained debate. There was curiosity that there was a statistically significant association between donors positive for anti-HBc and recipients with NANBH, just as there was between donors whose ALT levels were elevated and NANBH – but that there seemed to be only a limited overlap between them. Were they markers for different viruses? If introduced, would ALT and/or anti-HBc testing actually be effective at reducing cases of disease? This efficacy had not been proved in the only way it could be, by a prospective randomised controlled study.

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*to be hepatitis by clinicians or are not even thought to be serious enough for the patients themselves to seek medical attention.”* Gillon et al, Dow et al *Letters to the Editor on Non-A Non-B Hepatitis Surrogate Testing of Blood Donations* The Lancet 13 June 1987 p1 PRSE0002104

389 The Penrose Inquiry Final Report March 2015 p1234 PRSE0007002

390 Quite apart from the matters highlighted in the text, the aim of the study was “*to determine whether unrecognised viruses are circulating in the Scottish population resulting in cases of hepatitis which at present cannot be categorised. Other aims include identifying whether such viruses have a carrier state*”. Non-A, non-B Hepatitis in the West of Scotland July 1984 p4 PRSE0002577. It does not seem to have addressed the first by any reliable examination of cause and effect, and seems to express no conclusion on the first “*other aim*” or to have devoted any research liable to detect it.

391 Dow *Non-A, Non-B Hepatitis in West Scotland* October 1985 p16 PRSE0003937. It is right to note that six of the cases of NANBH identified were notified only as a result of his study.

392 Dr Dow himself said (to Lord Penrose, in evidence) that he thought that surrogate testing would have been likely to reduce the incidence of post-transfusion NANBH in Scotland by 70%. He expressed surprise that his work had been used as a basis for decision-making. Dr Brian Dow Penrose Inquiry Transcript 22 November 2011 p35, pp65-66 PRSE0006067



## 1986: surrogate screening re-considered

In 1986, the international position on surrogate screening for NANBH changed when the US moved towards introducing it.

The evolving views of some of those closely involved in this issue in the US are reflected in an article by Dr Alter and Dr Jules Dienstag, published in early 1986. This recorded that a small number of US blood centres had, following the TTV and NIH studies, adopted routine ALT testing; however none had performed a randomised controlled trial to determine if actual efficacy confirmed the efficacy predicted in the studies. The article also recorded that the NIH and TTV study groups had analysed the impact of testing donors for anti-HBc: *“Paradoxically, it was demonstrated that this HBV marker in the donor correlated strongly with the development of NANB hepatitis in the recipient.”* Whatever the reason for the association, the statistical relationship between donor anti-HBc and recipient NANBH was even stronger than that for ALT, and the predicted efficacy was in the range of 40%.<sup>393</sup>

The article went on to note that both ALT and anti-HBc tests had disadvantages: they had relatively low sensitivity and specificity and a very low positive predictive value. It was estimated that adopting the anti-HBc test would result in the initial loss of 4-8% of the donor population and the sustained loss of probably 2-4%. Cost and time were other disadvantages. The article continued: *“Despite these negative features, however, the accumulating data that chronic NANB hepatitis leads to cirrhosis in 10 to 20% of cases has served as compelling evidence for the need to rely on indirect assays as an interim measure until such time as specific NANB hepatitis assays are developed.”* While the adoption of these two tests represented a *“very complex and difficult decision”*, *“increasing documentation of the chronic sequelae of NANB hepatitis and the continued high incidence of this disease after transfusion have tipped the balance in favour of adopting indirect assays for NANB hepatitis carrier detection.”*<sup>394</sup>

The FDA considered the introduction of NANBH surrogate testing in mid February 1986. It was known in the UK that this was to take place. On 17 February 1986 Dr Cash wrote to Dr Gerald Sandler of the American Red Cross (“ARC”) to ask for news of the outcome of the FDA’s deliberations and whether the ARC had decided to introduce routine anti-HBc testing of donations.<sup>395</sup>

393 Dienstag and Alter *Non-A, Non-B Hepatitis: Evolving Epidemiologic and Clinical Perspective Seminars in Liver Disease* 1986 p10 PRSE0000340. In a retrospective publication published in 1998, Dr Alter and Dr Leonard Seeff made specific reference to a third study, conducted in Germany, which measured the impact of adding anti-HBc testing to the screening of a population already tested for ALT. It showed that recipients of anti-HBc positive blood had a fivefold greater risk of developing post-transfusion hepatitis than recipients of blood testing negative. Though they plainly regarded this as important in the history of the US’s move towards introducing surrogate testing, there is scant reference to it in any of the UK debates. If there had been, it would have been further confirmation of the potential value of surrogate screening. Alter and Seeff *Transfusion-Associated Hepatitis Clinical Aspects of Viral Liver Disease* p8 NHBT0000117\_047

394 Dienstag and Alter *Non-A Non-B Hepatitis: Evolving Epidemiologic and Clinical Perspective Seminars in Liver Disease* 1986 p10 PRSE0000340

395 Letter from Dr Cash to Dr Sandler 17 February 1986 SBTS0000433\_022. Dr Sandler replied by letter dated 4 March 1986: the ARC had not changed its approach to donor testing at this time but would



## The FDA recommends surrogate screening

On 21 February 1986, *Blood Bank Week*, published by the American Association of Blood Banks (“AABB”), announced that the FDA’s Blood Products Advisory Committee would recommend the introduction of both ALT and anti-HBc testing of blood donations. The Advisory Committee had considered reports of two studies showing that recipients of blood from donors with elevated ALT and anti-HBc had a higher incidence of NANBH. While questions had been raised about the data, it was noted that “*the carrier rate of NANB is higher than previously thought, that cases are underreported and that NANB is now considered to be a much more serious disease.*”<sup>396</sup>

The FDA’s recommendation was soon discussed in the UK. It was circulated, for example, for the 25 March 1986 SNBTS directors’ meeting. In addition, following a discussion of developments in the US, Dr Brian McClelland reported that he would be able to provide data about raised ALT levels in blood donors by the autumn of 1986, following a successful Ethics Committee proposal.<sup>397</sup> Dr John Forrester (attending on behalf of the SHHD) was reported to have said that he would be glad to hear of any research but could not guarantee funding.<sup>398</sup> The directors agreed to give consideration to funding someone to undertake research and Dr Cash would think about the possibilities and make some proposals to them.<sup>399</sup>

Meanwhile, the NIH group in the US published further results on the use of anti-HBc as a surrogate marker for NANBH. In an April 1986 article, published in the *Annals of Internal Medicine*, it reported an association between anti-HBc and NANBH. Rather than compare the relative merits of ALT and anti-HBc as screening markers, the article went on to discuss whether any indirect screening measure should be introduced. It noted that no specific assay for the agent(s) responsible for NANBH was available and none appeared imminent. A second important factor was developing knowledge of the clinical significance

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be reviewing whether to introduce anti-HBc/ALT donor testing imminently. Letter from Dr Sandler to Dr Cash MACK0002312

396 American Association of Blood Banks *Blood Bank Week No8* 21 February 1986 p2 PRSE0004555

397 Minutes of SNBTS meeting 25 March 1986 p8 ARCH0002254. Dr Brian McClelland explained in evidence that this was only a small element of his proposal for a comprehensive study. Dr Brian McClelland Transcript 28 January 2022 pp99-100 INQY1000178

398 The meeting minutes suggest a difference in approach emerging between the directors and Dr Forrester on the introduction of NANBH surrogate screening. They record Dr Forrester as having said that it was highly unlikely that the UK health departments would fund testing based on data from the US, in response to which “*it was recalled that HBs-Ag and AIDS antibody testing had both been introduced without UK research.*” It was also noted that “*Certain clinicians and haematologists in this country had felt that the Transfusion Services had been slow to commence AIDS antibody testing and others had similar views in relation to non-A non-B hepatitis surrogate tests.*” Dr Forrester’s apparent scepticism about the introduction of surrogate screening was reflected in his note of the meeting, shared with SHHD colleagues, in which he commented that there was “*no justification for panic measures.*” Letter from Dr Forrester to Dr Archibald McIntyre 26 March 1986 p2 PRSE0003127. Relying on Dr Dow’s thesis, Dr Forrester stated in his note that the number of cases in Scotland due to blood transfusion was “*probably exceedingly low*”. The day after the meeting, Dr Forrester wrote to Dr Dan Reid of the Communicable Diseases Surveillance Unit in Glasgow, seeking information on: a) the likely incidence of NANBH in Scotland; b) the proportion of NANBH attributable to blood transfusion or administration of blood; and c) how far any proposed test could reduce this proportion. Letter from Dr Forrester to Dr Reid 26 March 1986 PRSE0003198

399 Minutes of SNBTS meeting 25 March 1986 p8 ARCH0002254

of transfusion-associated NANBH. Virtually every study that had investigated the chronic sequelae of NANBH had confirmed that “*an inordinately high percentage of patients develop chronic hepatitis*”; that liver biopsies in patients with chronic ALT elevation showed chronic active hepatitis as the predominant lesion; and that 10-20% of those who had had biopsies had evidence of cirrhosis. While the cirrhosis tended to be clinically mild, deaths were being reported. If surrogate screening could prevent approximately one third of transfusion-associated cases of NANBH, this could represent an annual reduction of 50,000 cases of hepatitis and 2,500 cases of cirrhosis in the US. The authors commented that the “*potential to achieve this degree of disease prevention now appears to outweigh the disadvantages inherent in the adoption of surrogate tests for the non-A, non-B virus carrier state.*”<sup>400</sup>

### The UK: still debating further study

In the UK, however, the focus of discussion remained on whether further studies should be undertaken, and if so of what type. On 24-25 April 1986 the regional transfusion directors of England and Wales held a meeting. Dr Gunson explained that he had agreed with Scottish directors to raise the question of whether the National Blood Transfusion Service (“NBTS”) should carry out a study on NANBH. He reminded the regional transfusion directors of “*two previous attempts, one by the MRC and one by the Transfusion Associated Hepatitis Working Party, to study this problem.*”<sup>401</sup> The minutes record that, after discussion, it was “*agreed that this should not be pursued because of lack of time and resources.*”<sup>402</sup>

Some, however, considered that further study relevant to NANBH surrogate screening was necessary. A 23 May 1986 letter from Dr (later Professor Dame) Marcela Contreras (of the North London Blood Transfusion Centre) to Dr Alison Smithies at the DHSS provides an illustration of this view: Dr Contreras believed that a study of anti-HBc in British blood donors, as well as follow-up of recipients of anti-HBc positive donations, should be undertaken.<sup>403</sup>

In Scotland, the difference in approach between the SHHD and certain SNBTS directors that had previously begun to appear became more apparent. In May 1986, Dr Dow produced a report on NANBH surrogate screening for SNBTS directors. This suggested that the introduction of surrogate screening “*would have little impact on reducing the already low level of NANB PTH [non-A non-B post-transfusion hepatitis] cases at present reported within the West of Scotland region.*”<sup>404</sup> The SHHD relied to a significant extent on these views and

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400 Koziol et al *Antibody to Hepatitis B Core Antigen as a Paradoxical Marker for Non-A, Non-B Hepatitis Agents in Donated Blood* Annals of Internal Medicine April 1986 p7 PRSE0001533

401 Whilst Dr Gunson was correct in noting that the MRC had attempted to study this problem, the discussions by the Transfusion-Associated Hepatitis Working Party were just that – discussions, with no substantive attempts at study undertaken.

402 Minutes of Regional Transfusion Directors meeting 24-25 April 1986 p7 CBLA0002307

403 Letter from Dr Contreras to Dr Smithies 23 May 1986 NHBT0057025\_001. In the same letter, she suggested that, following the introduction of HTLV-3 screening, there was “*pressure to introduce screening to reduce the incidence of post-transfusion non-A non-B hepatitis.*” Professor Contreras’ recollection, in her oral evidence to the Inquiry, was that this pressure came from liver disease specialists and from haemophilia centre directors. Professor Dame Marcela Contreras Transcript 3 December 2021 p51 INQY1000166

404 Surrogate Tests for Non-A, Non-B Hepatitis May 1986 p3 PRSE0002544

the earlier work of Dr Dow, as well as input from Dr Follett and Dr Dan Reid. The echoes of the West of Scotland studies of 1984 and 1985 which were flawed because of their central reliance on the **reporting** of cases continued to reverberate. This can be seen, for example, in a 12 June 1986 internal SHHD minute by Dr Forrester, describing transfusion-associated NANBH as very uncommon in the west of Scotland. The minute referred to Dr Dow's view that the cost of surrogate screening in Scotland would be extremely high and the benefit minimal. Dr Reid and Dr Follet were also said to be against the introduction of ALT testing.<sup>405</sup>

Dr Cash took a different position. He expressed his views on the UK's approach to the introduction of NANBH surrogate screening in his characteristic style in a 28 August 1986 letter to Dr Ian Fraser at the Bristol Regional Transfusion Centre: *"I have a feeling that as the drums are beating louder and louder in other parts of the world on this topic the Brits remain fast asleep."* Dr Cash described his understanding that a proposal to establish a UK prospective trial at an earlier National Blood Transfusion Service ("NBTS") directors' meeting *"went down like the proverbial lead balloon!"* and proposed that the issue be revisited.<sup>406</sup> Dr Fraser's response of 4 September confirmed the lack of enthusiasm for a study amongst other regional transfusion directors in England and Wales: only he and Dr Contreras had supported it and the rest of the directors *"were not very interested."*<sup>407</sup>

Dr Contreras wrote to Dr Smithies again on 18 September 1986, enclosing a proposed pilot study of post-transfusion NANBH which she said should involve a maximum of two regional transfusion centres ("RTCs"). She noted that she had had *"some semi-political questions asked about the lack of screening in the UK when compared with the USA and I feel it is very important to have some hard data in this country."* Dr Contreras added that she was *"optimistic that a well designed trial may show that a surrogate screening for NANB hepatitis carriers in blood donations in this country is neither indicated nor cost effective."*<sup>408</sup>

Notwithstanding these views, by the time of their 8 October 1986 meeting, regional transfusion directors for England and Wales appear to have considered the introduction of surrogate screening to be *"very likely"*. The chair, Dr Fraser, reminded the meeting that there had been previous discussion of anti-HBc screening and that studies of the incidence of anti-HBc in the donor population had been undertaken at Edgware, Bristol and Manchester about three years earlier. It was said that *"Developments in America meant that this topic must be considered again as anti-HBc/ALT screening were soon to be essential for the accreditation of Blood Banks in the U.S.A."* Dr Fraser proposed that the DHSS be approached to fund a prospective study of 10,000 donations to examine whether the incidence of anti-HBc had changed since the earlier studies, involving Edgware, Bristol and possibly Manchester. The

405 Note on transmission of NANBH via blood and blood products 12 June 1986 PRSE0000857

406 Letter from Dr Cash to Dr Fraser 28 August 1986 PRSE0002109. On the same date, Dr Cash wrote to Dr Sandler of the ARC to obtain clarification of the US approach to surrogate screening. Letter from Dr Cash to Dr Sandler 28 August 1986 SBTS0000620\_146. He received a detailed response by letter dated 15 September 1986. Letter from ARC to Dr Cash 15 September 1986 MACK0002297

407 Dr Fraser was in favour of a further meeting and suggested that collaboration with Dr Contreras and Dr Richard Tedder might be possible. Letter from Dr Fraser to Dr Cash 4 September 1986 PRSE0003936

408 Letter from Dr Contreras to Dr Smithies 18 September 1986 p1 PRSE0003557

minutes went on to state that *“even if the incidence had reduced significantly since the last trial, because of self exclusion or for other reasons, the introduction of anti-HBc/ALT screening seemed very likely.”*<sup>409</sup>

This proposed study of ALT and anti-HBc levels in donors was also discussed at the 9 October 1986 SNBTS directors’ meeting, attended by Dr Gunson and Dr Fraser, with the latter suggesting that it would be helpful for an SNBTS centre to join it. The question of which body should take this issue forward was also raised. It was agreed that the UK Working Party on Transfusion-Associated Hepatitis was the most appropriate body to pursue the implementation of surrogate testing and that Dr Cash should write to Dr Gunson on behalf of SNBTS directors formally requesting the Working Party be reconvened, with a view to making proposals to the DHSS.<sup>410</sup>

### **The Working Party on Transfusion-Associated Hepatitis**

The Working Party on Transfusion-Associated Hepatitis was reconvened as suggested, having last met in 1983. Ahead of its first meeting, Dr Gunson prepared a paper, dated October 1986, on proposals for a multi-centre study of ALT and anti-HBc screening. This suggested that an important step before deciding whether or not to introduce surrogate screening was *“to examine a sample of the current donor population to determine the distribution of abnormal ALT levels and the presence of anti-HBc, and to study such donors in order to try to establish the presence or absence of disease.”*<sup>411</sup>

At the top of Dr Gunson’s *“Matters for Consideration”* in his paper was this assessment:

*“The best estimate of incidence from published data is 3%. If one assumes that the 2.3 million donations in the U.K. are transfused to 750,000 recipients annually, (possibly a more accurate assessment should and could be made), then one would expect 22,500 icteric or anicteric cases of NANB hepatitis each year. If the morbidity pattern of the disease is similar to that in the U.S.A. then one might expect half of these patients to have chronic ALT elevation and 10%, i.e. 2250, to develop cirrhosis [sic] ... If 30-40% of NANB hepatitis could be prevented by the use of the above tests, then the reduction in the number of cases would be 6750-900 [sic] per year and by extrapolations; 675-900 cases of cirrhosis [sic].”*

He made three qualifications to his assessment which led him to question whether the incidence was as high as his estimates suggested. Such data as was available was gathered before the measures introduced because of AIDS to exclude high-risk donors. The studies were often about multiply transfused patients and there was a clear dose relationship. He

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409 Minutes of Regional Transfusion Directors meeting 8 October 1986 pp7-8 CBLA0002345

410 Minutes of SNBTS Directors meeting 9 October 1986 p5 PRSE0001880

411 Alanine amino-transferase (ALT) and anti-hepatitis B core (anti-HBc) screening of blood donations 1 October 1986 p3 PRSE0002161



also noted that approximately half of patients died of their primary disease within one year of transfusion.<sup>412</sup>

The paper also proposed that the study evaluate the cost of performing the tests and their effect on “*donor management*”, as well as the effects that routine ALT and anti-HBc screening would have on blood donor panels. As for size, the study proposed the collection of 3,000 donor samples from each of four RTCs, including one in Scotland.<sup>413</sup>

The meeting of the reconvened Working Party took place on 24 November 1986. It discussed Dr Gunson’s proposal, and the possible introduction of surrogate screening more generally. According to the minutes, the Working Party considered that the US experience did not relate to the UK – on the basis that Hepatitis B rates were higher in the US and that any NANBH viruses prevalent in one country would not necessarily be equally prevalent in the other – and that “*the limited UK data did not of itself warrant introduction of anti-HBc/ALT screening at this time.*”<sup>414</sup> As for potential studies, it was agreed that a full prospective study of a group of recipients of all transfused blood or component units along the lines of the US TTV study would be “*too expensive and inappropriate in the UK.*” However, it was noted that a funding application for a study to follow up recipients of elevated ALT and anti-HBc positive units, together with controls, had already been submitted by the North London Blood Transfusion Centre.<sup>415</sup> As a “*first step*”, a meeting was proposed for 10 December 1986 to discuss a protocol for Dr Gunson’s proposal to screen 3,000 donors at each of four RTCs. It was noted that this study would gather current information on the prevalence of surrogate markers in different areas in the UK and follow up “positive” donors prospectively. It was also said that, in the absence of more data, meaningful comparisons of the money spent on the surrogate testing of donors versus the costs of treating acute and chronic post-transfusion NANBH could not be made.<sup>416</sup>

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412 Alanine amino-transferase (ALT) and anti-hepatitis B core (anti-HBc) screening of blood donations 1 October 1986 p13 PRSE0002161

413 Alanine amino-transferase (ALT) and anti-hepatitis B core (anti-HBc) screening of blood donations 1 October 1986 p3 PRSE0002161. The paper set out the background to the issue in some detail. It noted that in 1986 the AABB had announced its intention to screen donations for ALT and anti-HBc, with an implementation date of November 1986. It also recorded that donations screened by the ARC would be screened for ALT and that the AABB had subsequently deferred anti-HBc screening “*in order to resolve the problem of false positive reactions.*” The paper further noted that both West Germany and Italy carried out routine screening.

414 The minutes record various other aspects to the discussion. For example, Dr Barbara reported that “*many workers in the USA felt that surrogate screening had been introduced prematurely*” and that problems included: high false-positive anti-HBc rates with enzyme-linked immunosorbent assay (“ELISA”) tests compared with RIA; uncertainty about and variation in the ALT cut-off; inadequate facilities or instructions for donor management after “positive” results were recorded; uncertainty about how to take account of the other “non-specific” factors that might be causing ALT elevations; and a reduction in the supply of transfusable blood since anti-HBc and elevated ALT were largely independent factors. Minutes of UK Working Party of Transfusion-Associated Hepatitis meeting 24 November 1986 pp2-3 NHBT0000023\_007

415 The minutes record that Dr Brian McClelland expressed reservations about “*the value of too small a study which might not have the power to answer the necessary questions, either in domestic debate or at an international level.*” Minutes of UK Working Party of Transfusion-Associated Hepatitis meeting 24 November 1986 pp3-4 NHBT0000023\_007

416 A note of the meeting prepared by Dr Brian McClelland recorded that it had been agreed that “*Screening should not be introduced at present especially in view of ARC postponement of core test start-up and reports of chaos in ALT screening programme.*” Memo from Dr Brian McClelland



In oral evidence to the Inquiry, commenting on this timeline, Dr Brian McClelland accepted that nothing had really moved on since the beginning of the 1980s. He described what was recorded in the minutes of the Working Party’s meeting as “*going round in very small circles some distance away from the target*”.<sup>417</sup>

There was, moreover, an important omission in the multi-centre study discussed at the Working Party’s 24 November 1986 meeting: it did not propose any follow-up of recipients. This point was made in a 1 December 1986 letter from Dr Contreras, who had not attended the meeting, to Dr Smithies. Dr Contreras explained that she and Dr (later Professor) John Barbara accepted that a fully prospective study, following up a cohort of recipients of **all** transfused units (as with the TTV study), would involve enormous cost. However, this did not preclude “*some form of specific prospective follow-up of recipients of the actual ‘positive’ units together with limited controls.*” She suggested that it would be pointless merely to assess anti-HBc and ALT rates in donors. Doing so was “*simply a first (albeit important) step towards providing hard data for replying to the question:- ‘Should the UK be performing surrogate screen tests for NANB hepatitis?’*”<sup>418</sup>

During a discussion of the proposed four-centre study at the 21 January 1987 meeting of regional transfusion directors for England and Wales, Dr Gunson explained that a study beginning with transfused patients had been discussed but was felt to be “*costly, difficult and not practical.*”<sup>419</sup> A draft protocol for the proposed study was discussed in more detail at the 22 January 1987 meeting of the Transfusion-Associated Hepatitis Working Party.<sup>420</sup>

Accordingly, as of January 1987, what was being considered was an approach for funding to undertake a study relevant to surrogate screening for NANBH. No funding had been obtained and the study had not begun. The actual introduction of surrogate screening was not even under contemplation. In oral evidence to the Inquiry, Professor Contreras commented that, looking at the matter now, it was “*taking far too long.*”<sup>421</sup>

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on screening to reduce PTH NANB 2 December 1986 p1 SBTS0000370\_068. Dr Forrester’s SHHD note stated that the Working Party had explicitly decided “*to recommend research of no great significance or scientific interest because the prospect of research would serve to counter pressure from for example haemophiliacs and Haemophilia Directors to embark on an indirect and largely ineffective form of screening, which would also lose us a certain amount of perfectly harmless blood.*” Dr Forrester’s note also stated that he had asked Dr Gunson if he would advise screening if it were free of cost and that Dr Gunson had said “*No*”. Letter from Dr Forrester to Dr McIntyre 1 December 1986 p2 PRSE0003801

417 Dr Brian McClelland Transcript 28 January 2022 p103 INQY1000178

418 Dr Contreras added: “*Finding ‘positive’ rates without having any idea of whether these positives actually transmit NANB hepatitis in the UK will provide no defence against ‘panic’ requests to start surrogate screening.*” Letter from Dr Contreras to Dr Smithies 1 December 1986 p1 NHBT0000014\_097

419 Minutes of Regional Transfusion Directors meeting 21 Jan 1987 p2 CBLA0002358\_001

420 Minutes of Transfusion-Associated Hepatitis Working Party meeting 22 January 1987 pp1-2 PRSE0000450

421 Professor Dame Marcela Contreras Transcript 3 December 2021 p61 INQY1000166

## 1987: the multi-centre study and SNBTS divergence

Work on finalising the multi-centre study proposal continued in early 1987. However, it is also apparent that – at least in some quarters – the view that transfusion-associated NANBH was rare and the condition generally not serious continued to be influential.

This can be seen, for example, in the minutes of the 9 February 1987 meeting of SNBTS and haemophilia directors. When describing the background to the multi-centre study proposal, Dr Forrester reported that in the US between 5% and 25% of transfusions led to the recipient contracting NANBH. It was said that the figure in the UK was approximately 2.5% and, in Scotland, that there were only one to five cases per annum. NANBH was described as appearing to be “*relatively benign, despite some risk of cirrhosis of the liver in the long term, unless the recipient is pregnant when the effects can be very serious.*”<sup>422</sup>

In addition, Scottish involvement in the study came to be doubted around this time. In response to a request from Dr Forrester for agreement in principle that funding could be sought from the Chief Scientist’s Office (“CSO”) of the SHHD for the Scottish component of the study, Dr Elaine Moir expressed significant reservations.<sup>423</sup> This was on the basis that the proposed study would duplicate work previously carried out by Drs Follett and Dow.<sup>424</sup> The echoes of that work continued to reverberate.

Nonetheless, a suggestion that the time for further research had passed began to emerge. This was reflected in a striking and unexpected passage in the minutes of the 3 March 1987 SNBTS directors’ meeting. The minutes recorded the directors’ agreement: “*To recommend to the SHHD that surrogate testing for NANB should be implemented with effect from 1 April 1988 as a national development requiring strictly new funding.*”<sup>425</sup> Directors were asked to let

422 Minutes of SNBTS Directors and Haemophilia Directors meeting 9 February 1987 p3 PRSE0002769. Similarly, see a 26 January 1987 internal SHHD document written by Dr Forrester, in which he described NANBH as “*a residual rag-bag when Hepatitis B and Hepatitis A are excluded*” which was “*relatively benign.*” Material for Prime Minister’s Office Report PRSE0001376

423 Memo from Dr Forrester to Dr Moir 10 February 1987 PRSE0002803, Memo from Dr Moir to Dr Forrester 17 February 1987 PRSE0002361. Dr Moir was director of the CSO.

424 As explained further below, doubt over Scottish involvement in the multi-centre study continued for some time before it was confirmed that no Scottish RTC would participate.

425 Minutes of SNBTS Directors meeting 3 March 1987 p6 PRSE0004163. In a 21 April 1987 letter to Professor Cash, commenting on the minutes, Dr Gunson wrote that it was incorrect to state, as the minutes did, that “*no Scottish Centre was now being asked to participate*” in the multi-centre study. While the number of tests and location of the testing proposed in the study had changed, the Edinburgh RTC remained part of the study’s funding proposal. Dr Gunson added that he was “*dismayed*” to read that the SNBTS was putting forward proposals for the funding of surrogate tests from 1 April 1988; he had understood that “*Scotland would not take unilateral action*” in introducing surrogate testing without consultation with regional transfusion directors in England and Wales. Letter from Dr Gunson to Professor Cash 21 April 1987 PRSE0001289

In response, Professor Cash suggested that Dr Gunson should not take the content of the minutes in relation to surrogate testing “*too seriously at this stage. I think it would be appropriate to say that it was a decision made with our PESC [Public Expenditure Survey Committee] submission in mind and, I suspect, a view that we have often expressed – that the results of the UK study are unlikely to have a material affect [sic] on future operational practice.*” He also thanked Dr Gunson for his correction on the SNBTS being involved in the UK study. Letter from Professor Cash to Dr Gunson 27th April 1987 PRSE0002017. The meeting was also attended by Dr Morris McClelland, Director of the Northern Ireland Blood Transfusion Service. In oral evidence to the Inquiry, Dr Morris McClelland explained that he could not recall whether he agreed with the recommendation made by SNBTS directors. More

Dr Cash knew what funds would be required in their region, assuming that both anti-HBc and ALT would be undertaken. An earlier part of the minutes noted that “*some commercial plasma collectors and non-profit blood collectors in the US had begun surrogate testing in 1987 and that in Britain the Haemophilia Society may adopt a position which put pressure on BPL [the Blood Products Laboratory] to ensure surrogate testing was introduced.*”<sup>426</sup> Otherwise they contained little detail on the reasoning behind the directors’ recommendation.<sup>427</sup>

On 28 April 1987, Dr Gunson completed the funding application to the DHSS for the multi-centre study.<sup>428</sup> As well as his own Manchester RTC, it was proposed that the study would involve the South Western, North West Thames and South East Scotland RTCs, and that it would determine the ALT levels of 12,000 donors and test for anti-HBc in 3,600 donors. Donors with an abnormal ALT value or who were anti-HBc positive would “*be asked to have a clinical examination and undergo further tests in order to determine, if possible, the significance of the results in terms of transmission risk of hepatitis.*” It was suggested that the study would be of value “*in assessing the effects on donor panels and their management, the cost and, possibly, the value of introducing routine screening of blood donations for ALT and anti-HBc.*”<sup>429</sup>

### Debate in *The Lancet* and at the Council of Europe

A year was to pass before the DHSS provided funding for the multi-centre study.<sup>430</sup> In the meantime, the debate about the introduction of NANBH surrogate screening began to play out in a series of letters to *The Lancet*. The first, by Dr Contreras and colleagues at the North London Blood Transfusion Centre, published on 18 April 1987, proposed further study. It concluded by commenting that if “*the true incidence of post-transfusion NANB hepatitis and its serious clinical sequelae are at a much lower level than reported from the USA,*

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generally, he did not believe that serious consideration was given to the introduction of surrogate testing for NANBH in Northern Ireland. While he and his colleagues were “*keeping a very close eye on the developments*”, they would have followed “*national decision-making.*” Dr Morris McClelland Transcript 1 February 2022 pp133-134 INQY1000179

426 Minutes of SNBTS Directors meeting 3 March 1987 p6 PRSE0004163

427 A 7 April 1987 internal minute from Dr Graham Scott provides some insight into the SHHD’s reaction to this development. He wrote: “*We must do whatever we can to prevent the BTS going ahead with a full scale introduction of this testing – or at least trying to blackmail us into the provision of funds.*” Memo from Dr Scott to Dr McIntyre 7 April 1987 PRSE0002916

428 The part of the application relating to costs was not finalised until 13 May 1987. Application for a research grant 13 May 1987 pp1-3 NHBT0000072\_002. The application was submitted to the DHSS on 15 May 1987. Letter from Dr Gunson to Office of Chief Scientist 15 May 1987 DHSC0002492\_051. No formal research proposal with a request for funding was put to the DHSS prior to this proposal.

429 Application for a research grant 28 April 1987 pp1-3 NHBT0000072\_002

430 The approval for funding was delayed by, among other things, taking four months to seek the views of external reviewers and then the need to address the comments of an external reviewer and SHHD’s biomedical committee, which caused the project to slip to the next financial year. As a result, approval for exceptional funding had to be sought from the DHSS’s Hospital and Community Health Services budget, which caused further delay. Letter from Dr Gravenby to Professor Florey 14 September 1987 DHSC0002492\_072, Memo from Dr Moore 27 November 1987 DHSC0002492\_090, Memo from Mr Harris Testing Blood Donations for ALT 29 January 1988 PRSE0000038

*then screening of donations to reduce the incidence of NANB hepatitis may not be cost effective in the UK.*<sup>431</sup>

Two months later, two further letters appeared arguing against the introduction of surrogate screening, at least without further study. The first, by Drs Dow, Ruthven Mitchell and Follett of Glasgow, stated that the authors had found a very low incidence of reported<sup>432</sup> cases of NANBH in West Scotland. They suggested that it would *“be prudent to do a UK study to assess the real incidence of acute post-transfusion NANB hepatitis and to assess the proportion of those chronically affected, before considering following the American surrogate testing policy.”*<sup>433</sup> The second, by Dr Jack Gillon and colleagues in Edinburgh, reported the results of ALT and anti-HBc testing carried out between April and November 1986. This was said to have found a strong association between raised ALT and both obesity and alcohol ingestion, suggesting that these two factors might account for 82% of the abnormal ALT values found. The letter highlighted the tendency of ALT levels to fluctuate and suggested that the loss of donated blood *“would be far in excess of that suggested by published studies, and most of the excluded donors would not be NANB hepatitis carriers.”* The authors further highlighted the cost of surrogate screening and the consequences of *“identifying up to 5% of the donor population as being potential carriers – not just the costs of further laboratory tests, clinical assessments, and counselling but also the anxiety raised in the donors themselves.”* Having regard to the limitations of the published US data, they concluded that *“the introduction of ALT/anti-HBc screening tests as an indicator of NANB hepatitis carrier status in blood donors cannot at present be justified.”*<sup>434</sup>

While this debate took place on the pages of *The Lancet*, the question of surrogate screening for NANBH was being considered at a European level. Following a meeting on 19-22 May 1987, the Council of Europe’s Committee of Experts on Blood Transfusion and Immunohaematology, which included Dr Gunson, published a report addressing surrogate

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431 The letter stated: *“Before we are forced to accept two screening tests of unproven benefit, which have high revenue implications, we need a national study to assess the incidence of raised ALT and anti-HBc in donors in different parts of the country. Also, and perhaps more importantly, a study is needed to assess the incidence of acute post-transfusion NANB hepatitis and to assess how many of those affected develop evidence of chronicity and serious clinical sequelae.”* Anderson et al *Letter to the Editor on Surrogate Testing for Non-A, Non-B Hepatitis* *The Lancet* 18 April 1987 NHBT0000025\_010

432 The finding is clearly right – very few such cases had been reported. What mattered however was how many had occurred, which was likely to be a very different picture. That was not an easy matter to determine.

433 Gillon et al, Dow et al *Letters to the Editor on Non-A Non-B Hepatitis Surrogate Testing of Blood Donations* *The Lancet* 13 June 1987 p1 PRSE0002104

434 Gillon et al, Dow et al *Letters to the Editor on Non-A Non-B Hepatitis Surrogate Testing of Blood Donations* *The Lancet* 13 June 1987 pp1-2 PRSE0002104



screening for NANBH.<sup>435</sup> Different approaches in Europe were discussed.<sup>436</sup> Overall, the Committee considered that it could not give “*a general recommendation*” on the introduction of surrogate screening; individual countries would have to assess the situation locally and decide on the appropriate action to take. It advised that: “*If a stance is taken that blood should have maximum safety then the tests would be introduced but the benefits derived from this testing would not be uniform throughout every country.*”<sup>437</sup>

In the UK, the potential introduction of surrogate screening was considered further at the 17 June 1987 meeting of the Advisory Committee of the NBTS, under the chairmanship of Dr Edmund Harris, Deputy Chief Medical Officer for England. Professor Cash reported that SNBTS directors were in favour of introducing screening in view of impending product liability legislation in 1988 and a wish not to fall behind the private sector.<sup>438</sup> Others were against the introduction of testing: Dr Smithies suggested that further research was necessary; Dr Gunson considered that its introduction would be premature and cause an unjustified loss of donations. The chair’s summary of the views expressed at the meeting was that if testing was introduced it should be national; that research on baseline data would be carried out; and that the position would be monitored in the UK and abroad.<sup>439</sup>

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435 Extract from the Report of the Committee of Experts on Blood Transfusion and Immunohaematology 10th Meeting 18 June 1987 SBTS0003040\_001. On 30 July 1987, Dr Gunson sent Dr Smithies a report of the Council of Europe’s Committee and commented: “*With respect to NANB hepatitis, the paper leaves as many questions unanswered as it answers and finally comes to a conclusion that is not particularly helpful in that each country has to make a decision for itself. However, at least the Committee were not influenced by West Germany, and particularly by France, in coming to a resolution that ALT and anti-HBc should be introduced uniformly throughout Europe. I suppose this may be helpful in a negative sort of way.*” Letter from Dr Gunson to Dr Smithies 30 July 1987 NHBT0008816\_001

436 A French representative, Dr Bahman Habibi, explained that the viral hepatitis study group of the French National Blood Transfusion Society had recommended the implementation of both ALT and anti-HBc testing of blood donors and that a decision by the French public health authorities was expected in the months that followed. At the time of the meeting, Belgium, West Germany, Luxembourg and some Italian regions were routinely testing blood donations for ALT levels. West Germany and Italy had both done so for some time.

437 The report also recorded a number of drawbacks to the introduction of surrogate screening, including that there was “*no guarantee*” that, in any given country, there would be a significant reduction in transmission of NANBH; that in some countries it could lead to “*a severe depletion of blood donors which may compromise the blood supply*”; and that, where it was introduced, provision had to be made for the interviewing, counselling and further medical treatment which might be required for donors found to have a raised ALT or who were anti-HBc positive. Extract from the Report of the Committee of Experts on Blood Transfusion and Immunohaematology 10th Meeting 18 June 1987 p5 SBTS0003040\_001

438 Others shared a concern about the impact that commercial manufacturers relying on surrogate screening would have on NHS blood services. This can be seen, for example, in a chain of correspondence between Dr Contreras and the DHSS in December 1987, in which she described herself as being “*dismayed and shocked*” to learn that commercial plasma fractionators had been permitted to state in their package inserts that their products were derived from donations which had been tested for ALT. Letter from Dr Contreras to Dr Frances Rotblat 14 December 1987 p1 NHBT0000187\_008, Letter from Dr Frances Rotblat to Dr Contreras 18 December 1987 NHBT0000187\_009, Letter from Dr Contreras to Dr Frances Rotblat 22 December 1987 NHBT0000187\_010. In a 17 December 1987 SHHD minute, copied to the DHSS, Dr Forrester suggested that this development would lead haemophilia clinicians and SNBTS directors to put pressure on the SHHD to agree to the introduction of surrogate screening. Memo from Dr Forrester to Mr Tom MacDonald 17 December 1987 PRSE0001159

439 Minutes of Advisory Committee on NBTS meeting 17 June 1987 p4 BPLL0007202



Another perspective subsequently appeared in the 4 July 1987 edition of *The Lancet*. The letter was authored by Dr Brian McClelland, Professor Cash and all the Scottish transfusion directors were signatories. It was entitled: “*Testing blood donors for Non-A, Non-B Hepatitis: irrational, perhaps, but inescapable*”. It accepted that the size of the benefit to be gained from surrogate testing could not accurately be established without a large prospective UK study to find out how many cases of post-transfusion hepatitis it would prevent. However, the letter argued that the time for such a study had passed: “*Starting now will give us an answer in 3-4 years – and that is probably 3 to 4 years too late.*”<sup>440</sup>

Three reasons were given for why the introduction of NANBH surrogate screening was “*virtually inescapable*”: the coming into force in 1988 of European legislation on strict product liability; that screening would improve the safety of pooled plasma fractions while waiting for the results of large-scale trials of heat-treated products; and the wishes of consumers to be supplied with NANBH-tested products. The article also sought to compare the cost of surrogate screening for NANBH with screening tests for HIV and Hepatitis B, suggesting that “*the cost of preventing morbidity by surrogate marker testing for NANBH may be no greater, and could be less, than those which are accepted for established screening programmes.*” The authors concluded that the decision which had to be made was “*when rather than whether the UK transfusion services follow the lead of the United States and other European countries in donor screening.*”<sup>441</sup>

In explaining to the Inquiry what had led him and his colleagues to write this letter, Dr Brian McClelland said that it was “*partly an element of extreme frustration at the fact that the appropriate epidemiological studies with donors and recipients had repeatedly not been done for – in the absence of any argument being raised against doing the study. And there had been repeated utterances by all sorts of people saying: what we really need is a prospective controlled study to see whether these tests are working or not.*”<sup>442</sup>

The letter generated a good deal of controversy. Reservations and disappointment were expressed at the 15 July 1987 meeting of regional transfusion directors for England and Wales, in particular at what was suggested to be unilateral action. Professor Cash, who

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440 McClelland et al *Letter to the Editor on Testing Blood Donors for Non-A, Non-B Hepatitis: Irrational, Perhaps, But Inescapable* *The Lancet* 4 July 1987 p1 PRSE0001444. Somewhat surprisingly, one of the authors of the letter was Dr Mitchell, who had co-authored a letter the previous month suggesting that further study should be undertaken before deciding whether to introduce surrogate screening. Gillon et al, Dow et al *Letters to the Editor on Non-A Non-B Hepatitis Surrogate Testing of Blood Donations* *The Lancet* 13 June 1987 PRSE0002104. Having been provided with a copy of the letter from Dr Brian McClelland and others, Dr Fraser expressed disappointment in a response to Professor Cash, particularly in light of his understanding that it had been agreed at the 10 June 1987 SNBTS directors’ meeting that there was “*a need for synchrony with England and Wales.*” Letter from Dr Fraser to Professor Cash 2 July 1987 PRSE0004482. In reply, Professor Cash stated that the SNBTS did not wish and currently had no intention of introducing NANBH surrogate testing unilaterally. He suggested that Dr Fraser should view the letter as part of a debate which had been initiated by earlier correspondence, and as a way to persuade the DHSS to give more thought to the issues. Letter from Professor Cash to Dr Fraser 8 July 1987 PRSE0001973

441 McClelland et al *Letter to the Editor on Testing Blood Donors for Non-A, Non-B Hepatitis: Irrational, Perhaps, But Inescapable* *The Lancet* 4 July 1987 pp1-2 PRSE0001444

442 Dr Brian McClelland Transcript 28 January 2022 pp106-107 INQY1000178

attended the meeting, indicated that he felt that he had had no alternative.<sup>443</sup> The SHHD was also concerned: in an internal minute, Dr Archibald McIntyre expressed concern that the SNBTS might seek to introduce surrogate testing without specific funding and agreement from the SHHD.<sup>444</sup>

On 1 August 1987, *The Lancet* published a further letter in response from Dr Contreras and Dr Barbara, arguing that “*Transfusion services must not bow to irrational pressure for measures whose efficacy is unproven.*” The letter called for the few available studies of transfusion recipients to be extended with a more complete follow-up of non-transfused patients, as well as suggesting that larger studies should be carried out before it was accepted that 50% of cases of post-transfusion NANBH progress to chronicity and that 10% of chronic cases progress to liver cirrhosis.<sup>445</sup>

In oral evidence to the Inquiry, Professor Contreras accepted that there was a problem with the approach described in her and Professor Barbara’s letter: namely, that it perpetuated a state of affairs in which there was no screening or testing for NANBH, which ran the risk of people continuing to be infected while waiting for a more complete understanding of the problem.<sup>446</sup> Professor Barbara accepted, also when giving evidence, that it was a premise of his and Professor Contreras’s argument that NANBH infections were occasional. He added that “*We also had the feeling that non-A, non-B was not as severe as hepatitis B.*”<sup>447</sup>

### Scottish participation in the multi-centre study

There was a degree of confusion in the spring and summer of 1987 as to whether a Scottish RTC would participate in the multi-centre study.<sup>448</sup> Contrary to earlier reports that the Edinburgh and South East Scotland RTC would not seek to join it, on 6 August 1987

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443 Minutes of Regional Transfusion Directors meeting 15 July 1987 p8 CBLA0002383

444 Dr McIntyre further noted that the DHSS had “*expressed their concern and dismay at the letter by Professor Cash and colleagues and have interpreted this as being SHHD policy; we have attempted to reassure them that it is not so. Their concern is that if we should commence testing unilaterally they will feel obliged to follow.*” Letter from Dr McIntyre to Duncan Macniven 21 July 1987 PRSE0004562

445 Contreras and Barbara *Testing of Blood Donations for Non-A, Non-B Hepatitis* *The Lancet* 1 August 1987 PRSE0003767

446 Professor Dame Marcela Contreras Transcript 3 December 2021 pp66-67 INQY1000166

447 Professor John Barbara Transcript 26 January 2022 p51 INQY1000176. Professor Barbara went on to describe his view of the value of surrogate testing being based on the limited number of post-transfusion hepatitis reports from clinicians, “*our perception of the limited clinical benefit and our awareness of the diversion of resources that introduction of surrogates would have entailed: cost, in other words.*” Professor John Barbara Transcript 26 January 2022 pp52-53 INQY1000176

448 This can be seen, for example, in a 14 May 1987 minute from Dr Forrester to Dr McIntyre, suggesting that the Scottish component of the study was being abandoned (which also referenced Dr Brian McClelland’s view that “*we had better simply institute screening*”): Memo from Dr Forrester to Dr McIntyre 14 May 1987 PRSE0001191; the minutes of the 10 June 1987 SNBTS Directors’ meeting, suggesting that previous minutes were incorrect and that Scotland was participating: Minutes of SNBTS Directors meeting 10 June 1987 p6 PRSE0000633; and a 19 June 1987 letter from Dr McIntyre to Professor Cash, setting out the former’s understanding that SNBTS now wished to proceed with the research project: Letter from Dr McIntyre to Professor Cash 19 June 1987 p1 PRSE0000140

Dr Brian McClelland and Dr Gillon applied to the Biomedical Research Committee of the SHHD's CSO for funding to enable the RTCs to participate.<sup>449</sup>

This funding application was ultimately rejected by the CSO's Biomedical Research Committee on 25 September 1987. Dr Forrester, who was present at the meeting which considered it, described the Committee as having rejected the application on scientific grounds, which he considered were "*substantial*".<sup>450</sup>

While it did not participate in the multi-centre study, the Edinburgh RTC was involved in a smaller study of blood donors around this time. This involved measuring ALT in 1,742 donors and anti-HBc in 2,086 donors between April and November 1986, with the paper describing the results received by *Vox Sanguinis* in October 1987 and published in 1988. The study found that 2.4% of donors had raised ALT level levels, of which 82% had a "non-viral" clinical explanation for this abnormality. Anti-HBc was found in 2% of donors and there was no overlap between donors with raised ALT and those with anti-HBc. The article's abstract summarised its conclusion as follows: "*In view of the medical and economic implications of the introduction of these screening tests, and the poverty of data on the clinical significance of post-transfusion non-A, non-B hepatitis, we conclude that such a screening programme cannot be justified at present. Further studies are required, including a prospective controlled trial of the effects of screening.*"<sup>451</sup>

449 Letter from Dr Brian McClelland to Dr William Forbes 6 August 1987 PRSE0001233, Application for CSO Biomedical Research Committee research grant 6 August 1987 pp1-11 PRSE0000365

450 Dr Forrester also suggested deferring the decision being announced until the CSO had coordinated its actions with the DHSS, and envisaged that the DHSS might wish to take over the research proposal by adding a fourth English centre to the study. His preference was to wait until these steps had been taken before reaching a decision on the SNBTS's request for money for screening. He also added a summary of the SHHD's position, which included that the gathering of the evidence necessary to decide whether to introduce surrogate screening, "*at least in Scotland, is obstructed by the inadequacies of the research proposal.*" Letter from Dr Forrester to Duncan Macniven 1 October 1987 p1 PRSE0004545. In a minute responding to Dr Forrester, Duncan Macniven mostly agreed but expressed concern about the anticipated timescale.

He commented that he was "*very anxious indeed for our decision (on whether or not to put resources into NANB testing) should be properly informed by research evidence*", as well as highlighting the "*substantial patient safety/expenditure issues which are at stake*". He suggested that "*the worst of all possible worlds is that research cannot get off the ground: I fear that, in those circumstances, we would be subjected to increasingly irresistible pressure to spend the money in any case, for the sake of improving (at any price) the safety of blood and blood products.*" Letter from Duncan Macniven to Dr Forrester 2 October 1987 PRSE0003515

The SHHD subsequently informed the DHSS of the decision of the CSO Biomedical Research Committee by letter dated 13 November 1987. The letter recorded that the Committee had decided that the funding application was fundamentally flawed and that, as a result, the applicants should not be allowed to resubmit. Letter from Dr Forbes to Dr Smith 13 November 1987 p1 PRSE0000359

451 Gillon et al *Post-Transfusion Non-A, Non-B Hepatitis: Significance of Raised ALT and Anti-HBc in Blood Donors* *Vox Sanguinis* 1988 p1 PRSE0002655. For another example of an article in this period calling for a prospective controlled study, see: Kitchen et al *Incidence and Significance of Hepatitis B Core Antibody in a Health Blood Donor Population* *Journal of Medical Virology* 1988 PRSE0002085. This study, which involved the North East Thames RTC, screened 1,893 donors for anti-HBc. 2.16% were found to be initially positive and 1.85% repeatably positive. In light of their findings and the "*very small number of cases of PTH [post-transfusion hepatitis] reported in the United Kingdom*" the authors considered "*that at the present time there is likely to be very little benefit in the introduction of anti-HBc screening of blood donors.*" They pointed to the loss of approximately 2% of available donors, the cost of testing donations and the need to counsel donors found to be anti-HBc positive. They concluded that: "*Although the introduction of surrogate testing may eventually be unavoidable, we believe that only a controlled prospective study would provide the necessary information to determine*

## 1988: the Chiron announcement and SNBTS convergence

In the autumn of 1987, SNBTS directors had rowed back on their previous recommendation that surrogate screening be introduced, agreeing in November that the financial year 1988/89 should be spent evaluating high ALT levels but not deferring positive donors.<sup>452</sup> The minutes of their 12 April 1988 meeting confirmed their agreement not to introduce screening in Scotland until it had become UK policy, though the directors wished to reserve their position in light of reports that ALT testing had commenced in at least one RTC in England and Wales.<sup>453</sup>

On 28 April 1988, almost a year after the application had been submitted, the DHSS granted funding for the multi-centre study.<sup>454</sup> Nonetheless, it seemed clear that a decision on whether actually to introduce surrogate screening was still some way off.<sup>455</sup> At the 5 May 1988 meeting of SNBTS and haemophilia directors, Dr Forrester said that a decision on the introduction of screening would probably wait until the outcome of the multi-centre study; Dr Brian McClelland and Professor Cash “*considered the delay unjustifiable*.”<sup>456</sup>

Alongside the UK’s work, consideration continued to be given to surrogate screening for NANBH at a European level. On 3-6 May 1988 the Council of Europe’s Committee of Experts on Blood Transfusion and Immunohaematology met again. A report of its meeting provides an overview of the approach already taken in different European countries to surrogate screening. In some countries no testing was undertaken. By contrast, ALT and/or anti-HBc screening were carried out in West Germany (where ALT testing had been in place since 1965), Italy (where ALT testing had been performed for 18-20 years and it was estimated that this had led to a considerable reduction in NANBH), Luxembourg (since 1986) and France (where ALT testing had been made compulsory in April 1988 and anti-HBc screening was being considered). Screening was shortly to be introduced in Malta and Switzerland. Countries in which some screening was carried out included Belgium (where approximately 25-30% of donations were screened for ALT) and Spain (where it was not compulsory but some centres performed ALT tests). Countries in which no routine screening was carried out included Cyprus, Greece, Iceland, the Netherlands, Norway and Finland.<sup>457</sup>

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*the significance of donor anti-HBc levels in relation to PTH, especially NANB, in the United Kingdom.”*  
Kitchen et al *Incidence and Significance of Hepatitis B Core Antibody in a Health Blood Donor Population* Journal of Medical Virology 1988 p6 PRSE0002085

452 Minutes of SNBTS Directors Co-ordinating Group meeting 10 November 1987 p4 PRSE0004522

453 Minutes of SNBTS Directors meeting 12 April 1988 p4 PRSE0003650. At the 14 June 1988 SNBTS directors’ meeting, the minutes record it was believed that the Birmingham RTC was about to begin routine testing of ALT and anti-HBc. Minutes of SNBTS Directors meeting 14 June 1988 p5 PRSE0003031

454 Letter from R Moore to D Allison NHBT0000014\_009

455 As noted below, the study did not begin until September 1988 and its full report was completed only in April 1990.

456 Minutes of SNBTS Directors and Haemophilia Directors meeting 5 May 1988 p5 SBTS0000832

457 The report is dated 15 September 1988 and appears to have been intended for distribution at a 21-24 November 1988 meeting of the European Health Committee. It was agreed that a questionnaire on the use of surrogate screening in different countries would be circulated prior to the Committee’s next meeting. European Health Committee Meeting Report 21-24 November 1988 pp18-20 NHBT0000018\_019. Dr Gunson subsequently analysed replies to this questionnaire in a paper



Meanwhile, further work was undertaken to get the multi-centre study up and running, with a meeting of its steering committee held on 8 June 1988. It was confirmed that Edinburgh had withdrawn: the participating RTCs were Manchester, Bristol and Edgware. The study protocol was discussed in detail and it was anticipated that screening would begin on 1 September 1988.<sup>458</sup> At the time of the 4 October 1988 meeting of regional transfusion directors in England and Wales, the results of the study were not expected before late spring 1989.<sup>459</sup>

### The Chiron announcement

By the time the multi-centre study began collecting data, an internationally significant development had taken place. On 10 May 1988, the Chiron Corporation announced that it had identified and cloned the NANBH virus, and that it had developed a prototype immunoassay that might lead to a (direct) screening test.<sup>460</sup>

Over the next 18 months or so, the introduction of surrogate screening for NANBH remained at least outwardly a possibility, though the issue came to be intertwined with the development of a screening test for the NANBH virus (or Hepatitis C, as it became known). For example, at a 13 December 1988 meeting of SNBTS directors, Dr Gunson explained that Chiron had agreed to test 1,000 randomly selected samples from the multi-centre study.<sup>461</sup>

Moreover, the question of whether to introduce surrogate screening (as well as anti-HCV testing) became part of the remit of two new UK-wide committees. These were the Advisory Committee on Transfusion Transmitted Diseases (“ACTTD”) and the Advisory Committee on the Virological Safety of Blood (“ACVSB”). The Scottish transfusion directors confirmed they would not start surrogate testing unless and until it was supported by the Department of Health and SHHD, which were to be advised by these new committees.<sup>462</sup>

## 1989: new committees and the rejection of surrogate screening

The first meeting of the ACTTD – attended by Professor Cash and Dr Contreras, Dr Follett, Dr Gunson, Dr Mitchell and Dr Phillip Mortimer – took place on 24 February 1989. They agreed no recommendation to introduce ALT testing would be made until the multi-centre study in England was completed. However, the minutes record a belief that surrogate screening might be introduced in response to the position taken in other countries in relation to plasma products. There was said to be “*a degree of inevitability about the introduction*

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which was shared with the Advisory Committee on the Virological Safety of Blood (“ACVSB”) in July 1989. Analysis of Replies to Committee of Experts in Blood Transfusion and Immunohaematology Questionnaire 27 June 1989 PRSE0003137, Minutes of ACVSB meeting 3 July 1989 p2 NHBT0000072\_025

458 Minutes of Steering Committee on Multi-Centre Study of ALT and anti-HBc Screening of Blood Donations meeting 8 June 1988 p4 NHBT0000187\_024

459 Minutes of Regional Transfusion Directors meeting 4 October 1988 p6 NHBT0018189

460 Chiron Press Release *Chiron Clones Hepatitis Non-A, Non-B Virus Which May Allow Screening for Previously Undetectable Disease* 10 May 1988 p1 PRSE0000842

461 Minutes of SNBTS Directors meeting 13 December 1988 p4 PRSE0001626

462 At their 13 December 1988 meeting. Minutes of SNBTS Directors meeting 13 December 1988 p4 PRSE0001626



*of the test which was required by regulatory authorities in other countries to determine the acceptability of fractionated plasma products.*<sup>463</sup>

The second committee, the ACVSB, met for the first time on 4 April 1989. A paper before it commented that the issue of surrogate testing for NANBH was “*of some urgency*” and suggested that it be a major item for the next meeting, even though a final decision might have to await the results of further research.<sup>464</sup> A paper provided to ACVSB members on 12 May 1989 explained that it was too early to report on the multi-centre study: it was hoped that a review would take place in June, although conclusions would not be drawn until the result of the Chiron tests on samples collected through the study were known.<sup>465</sup> At the ACVSB’s meeting on 22 May 1989, it was again agreed that surrogate screening should not be introduced before the results of the study were available. It was also noted that “*The use of Chiron or surrogate testing would be influenced by Chiron data once released*”.<sup>466</sup>

On 14-15 September 1989, Dr Gunson attended an international meeting in Rome to discuss the Chiron test/Hepatitis C virus. He subsequently prepared a paper, based on presentations at the meeting, which was considered at the ACTTD’s 9 October 1989 meeting. The paper addressed both Chiron’s test (now called the anti-HCV test) and NANBH surrogate screening. It included tables showing the correlation of ALT and/or anti-HBc with positive anti-HCV results in the UK (based on samples from the multi-centre study in England and a Scottish study). These showed some association between a raised ALT and positive anti-HBc on the one hand and positive anti-HCV results on the other. However, the majority of anti-HCV positives did not have non-specific markers. Dr Gunson recommended that routine screening of anti-HCV should be introduced when practical. By contrast, while noting that the topic would be kept under review, he recommended that the “*routine introduction of non-specific tests should be deferred, unless this is necessary for the acquisition of product licences in the U.K. for fractionated plasma products.*”<sup>467</sup> The ACTTD accepted Dr Gunson’s

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463 The minutes added that this would be discussed with the Blood Products Laboratory (“BPL”) in the near future. Agenda and Minutes of UK Advisory Committee on Transfusion Transmitted Diseases 24 February 1989 p5 NHBT0000043\_002. This issue was explored further at a 17 May 1989 meeting of the NBTS/Central Blood Laboratories Authority Liaison Committee. The minutes record: “*Dr. Gunson explained that from the point of view of the NBTS and its responsibility towards the recipient, it was the general view that the introduction of ALT testing was unnecessary. However, it was recognised that CBLA [Central Blood Laboratories Authority] requirements for the future sale of surplus products to other countries and the development of new products such as intra-venous immunoglobulins would require an ALT tested plasma.*” It was agreed that the issue would be considered further at another meeting. Agenda and Minutes of NBTS/CBLA Liaison Committee 10 August 1989 p3 NHBT0007355

464 Overview of Problems for this Committee p1 PRSE0004113, Minutes of ACVSB meeting 4 April 1989 p5 NHBT0000041\_003. Dr Mortimer was the only member who was also a member of the ACTTD. The membership of ACVSB was not focussed centrally on the supply of blood for transfusion, as was that of the ACTTD: it had two fractionators, one haematologist, as well as Professor Zuckerman, and representatives of the Public Health Laboratory Service (Dr Mortimer) and the National Institute for Biological Standards and Control.

465 Memo from Dr Andrzej Rejman and John Canavan to ACVSB members 12 May 1989 p2 NHBT0000061\_022

466 Minutes of ACVSB meeting 22 May 1989 p3 NHBT0005019

467 Report on the Meeting in Rome to Discuss Chiron Testing 10 October 1989 p7 DHSC0003557\_053

recommendations and conclusions: the minutes record its agreement that his report should be used as the basis for a paper to be submitted to the ACVSB.<sup>468</sup>

The ACVSB was to meet on 6 November 1989. Dr Gunson prepared a paper for it in advance, summarising the results of the multi-centre study. This reported that the final report of the study was nearing completion and that, taken overall, 3.2% of donors would have been rejected for raised ALT and 0.63% for anti-HBc seropositivity. However, if a policy of only rejecting donors with a raised ALT on two successive samples were adopted (in line with the Swiss Red Cross), the figure would reduce to 1.1%. The paper commented that it was “*difficult to conclude*” how many donors with a raised ALT or who were seropositive for anti-HBc may have transmitted NANBH; for that to be determined a prospective study was required. It was noted that the correlation between ALT levels and alcohol intake and obesity was striking and that the significance of a positive anti-HBc result was unknown. The paper went on to describe the potential justification for introducing surrogate screening in light of the arrival of the anti-HCV test:

*“4.3 Following the introduction of the anti-HCV test the only justification for performing the ALT and anti-HBc tests routinely is:*

*4.3.1 The possibility that ALT (in particularly [sic]) will identify a “window” of infectivity prior to seroconversion for anti-HCV.*

*4.3.2 The possibility that anti-HCV only identifies one of a number of viruses which cause NANBH.*

*The introduction of other specific viral markers and increased sensitivity of the anti-HCV test in due course may render the subject of surrogate testing of academic interest. Meanwhile, the desirability of introducing these tests remains an issue of health economics.”*<sup>469</sup>

This report and Dr Gunson’s paper on the Rome meeting were discussed by the ACVSB. The ACVSB considered the Chiron/anti-HCV test to represent a “*major step forward*” but decided that it needed more information about it, as well as a confirmatory test.<sup>470</sup> While the Committee suggested that it would support the general introduction of the Chiron test if the FDA approved it, its “*feeling was that there was no case for using surrogate tests for NANB.*”<sup>471</sup>

This effectively marked the end of the UK’s consideration of whether to introduce routine surrogate screening for NANBH.

468 Minutes of ACTTD meeting 9 October 1989 p3 NHBT0000043\_034. The paper is dated 10 October 1989 – the day after the meeting. The minutes refer to an amended report from Dr Gunson: it therefore seems likely that it was amended following discussion at the meeting.

469 Minutes of ACVSB meeting 21 February 1992 p7 NHBT0000079\_033

470 See the chapter on *Hepatitis C Screening*.

471 Minutes of Advisory Committee on the Virological Safety of Blood meeting 6 November 1989 p5 NHBT0005043

## 1990: the multi-centre study's full report

The full report for the multi-centre study on NANBH surrogate screening was eventually completed in April 1990. It suggested that, despite the development of Chiron's anti-HCV test, screening for NANBH surrogate markers remained relevant: there were unresolved problems with the anti-HCV test, which might have limited sensitivity, and no confirmatory test was available; moreover, during the window period before seroconversion, which could last up to 12 months, there was no specific assay available to diagnose infection.<sup>472</sup>

It was reported that, out of 9,741 samples, the overall prevalence of raised ALT identified in the study was 3.1%.<sup>473</sup> The paper commented that whether or not ALT testing should be considered in the context of reducing the incidence of post-transfusion hepatitis had become “*even less clear*” since the development of the anti-HCV test. Nonetheless, it noted that “*if the desire to ensure a ‘minimum risk’ product overrides the economic and logistic considerations, ALT testing then becomes a serious contender, among the other aspirants, for entry in the list of microbiologically orientated screening tests.*”<sup>474</sup>

The initial anti-HBc overall positive screen rate was 1.3%, though this reduced following repeat reactive and confirmatory tests.<sup>475</sup> Having noted difficulties in determining the reliability of anti-HCV tests, the paper concluded that the value of anti-HBc as a surrogate marker for post-transfusion NANBH could “*only be assessed objectively in prospective PTH [post-transfusion hepatitis] studies in the country concerned, otherwise a high proportion of donors would be lost without knowing the real significance of a positive test in a given population.*”<sup>476</sup>

The paper also reported on the follow-up of donors with raised ALT levels. It concluded that the results confirmed previous reports that “*the vast majority of donors with raised ALT are obese and consume alcohol in excess.*”<sup>477</sup> However, the paper again commented that the results it presented could not resolve the question of whether NANBH surrogate screening should be introduced:

*“However from the findings of this study the issue of justifiability of ALT testing cannot be resolved. The main arguments for adoption of this test in the post HCV era are the ‘window of infectivity’, and the possibility of other NANB viruses causing PTH. Against ALT testing are the problems of non-specificity of the test, finance, donor loss and donor counselling. The introduction of other specific viral markers to narrow the ‘window of infectivity’ and exclude other viruses may, in due course,*

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472 Multi-Centre UK NANB Surrogate Marker Study April 1990 p3 PRSE0000290

473 This varied between North London (3.06%), Bristol (4.56%) and Manchester (1.97%). Multi-Centre UK NANB Surrogate Marker Study April 1990 p6 PRSE0000290

474 Multi-Centre UK NANB Surrogate Marker Study April 1990 p12 PRSE0000290

475 The initial rate varied between North London (1.8%), Bristol (0.93%) and Manchester (1.32%). Following confirmatory testing, the overall rate was 0.63%. Multi-Centre UK NANB Surrogate Marker Study April 1990 p22-23 PRSE0000290

476 Multi-Centre UK NANB Surrogate Marker Study April 1990 p27 PRSE0000290

477 Multi-Centre UK NANB Surrogate Marker Study April 1990 p44 PRSE0000290

*render the subject of ALT testing of only academic interest. In the meantime, the desirability of ALT or otherwise remains an issue of health economics.”<sup>478</sup>*

Accordingly, while suggesting that there remained potential justifications for the introduction of surrogate screening, the final report of the multi-centre study could not answer the crucial question of whether such screening was likely to reduce the incidence of transfusion-associated NANBH. In any event, by April 1990, the focus of the relevant advisory bodies and decision-makers in the UK had moved firmly to the question whether and when to introduce anti-HCV screening of blood donations.

## Commentary

Whether to introduce surrogate testing for NANBH in the UK was a complex decision.

Such decisions are best addressed by identifying the principles in play. The application of principle depends on the particular context.

The context in which this decision fell to be made is clear. By 1979 it was clear that NANBH was a serious disease with long-term consequences.<sup>479</sup> Although it tended to be mild in the acute phase, it was liable to cause persistent hepatic dysfunction leading to cirrhosis when it became chronic. By 1980, it was so clear to Dr Diana Walford at the DHSS that she wrote in a memo:

*“I must emphasise that 90% of all post-transfusion (and blood-product infusion) hepatitis in the USA and elsewhere is caused by non-A, non-B hepatitis viruses which (unlike Hepatitis B) cannot, at present, be detected by testing donor blood. This form of hepatitis can be rapidly fatal ... or can lead to progressive liver damage. It can also result in a chronic carrier state, thus increasing the ‘pool’ of these viruses in the community.”<sup>480</sup>*

If there had been a test available by 1979 to screen blood for NANBH it would before long have become universal in the UK. It is inconceivable that this would not have been the

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478 Multi-Centre UK NANB Surrogate Marker Study April 1990 p44 PRSE0000290

479 1979 was a year in which (a) Dr Peter Kernoff wrote of NANBH that: *“This is a serious disease with long-term consequences”*: Letter from Dr Kernoff to Dr Brian Colvin 27 April 1979 p2 BART0002487; (b) *The Lancet* published a report of an outbreak of NANBH saying that the data confirmed that *“this form of hepatitis may be related to a high frequency of persistent hepatic dysfunction”*: Dienstag et al *Non-A Non-B Hepatitis Associated With Chronic Liver Disease in a Haemodialysis Unit* 5 May 1979 p2 PRSE0002202; (c) Dr Kernoff and Dr Colvin wrote a paper for the Haemophilia Working Party of the North East Thames Regional Association of Haematologists that pointed to NANBH as the cause of a substantial proportion of cases of post-transfusion hepatitis negative for HBsAg. A distinction was clear between acute NANBH, which appeared generally mild, though might sometimes be fatal, and chronic NANBH in respect of which it seemed *“very possible that there may be serious long-term sequelae”*: Guideline from North East Thames Regional Association of Haematologists 16 May 1979 p1 BART0000684; (d) Dr Alter and others published: Alter et al *The Chronic Sequelae of Non-A, Non-B Hepatitis* *B Annals of Internal Medicine* July 1979 PRSE0001250; and (e) Dr Athol Ware and others showed that infection with NANBH accounted for *“much of [a] serious, often fatal, complication of renal transplantation”*: Ware et al *Etiology of Liver Disease in Renal-Transplant Patients* *Annals of Internal Medicine* September 1979 p1 PRSE0000631

480 Memo from Dr Diana Walford to Mr Harley 15 September 1980 p1 WITN0282008

case. That is so even if, in the nature of some early tests, it may have missed several infections, and might falsely have identified other donations as positive. This is what had happened with Hepatitis B some seven years earlier.<sup>481</sup> Knowing that it would detect less than half the infections in donations had not prevented the transfusion services introducing a test.<sup>482</sup> In short, if it were known that a test would identify a significant proportion of infected donations, so that patients would be spared the disease which might follow, one not only should but would have been introduced.

There was no screening test for NANBH/Hepatitis C until 1989.

Any decision-making about how to reduce the risk of a transfusion transmitting it before then had to assume in a context such as this that the disease could be a serious one, with significant long-term consequences, however mild they might hope that it might turn out to be. Protection against potential transmission of probably serious disease cannot assume there is nothing, really, to worry about.

### Principles of approach

As to the principles, then, which should have been applied by decision-makers in this context.

First and foremost, patient safety should have been the paramount, guiding principle.

Second, a search for certainty can be, and in this case was, an enemy of achieving progress.

Third, risks to public health need to be addressed with speed, consistency, and an objective look at such evidence as there is without making unjustified assumptions.

Fourth, what aids the process is a clear structure for decision-making. Instead of effective decision-making here, there was “decision paralysis”.

Finally, cost, though a relevant factor, should not be the starting point.

Sadly, these principles were honoured more in the breach than in the observance.

As to the principles of analysis by this Inquiry: in analysing whether, and to what extent, matters took a wrong turn, events are to be assessed by reference to the information which was reasonably available, or should have been, at the time. People cannot be judged by what they did not know, and had no basis to learn, whatever we may now realise.

However, any assessment of the principles applied by decision-makers at the time must apply the standards of today. In her oral evidence to the Inquiry Professor Contreras described the approach that she and her colleagues had taken previously in relation to surrogate testing. This was an approach of “*maximum benefit at minimal cost*”. She described her change of thinking by 1991:

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481 The tests for Hepatitis B, even by 1980, were far from capable of identifying every case correctly, even though they were a significant improvement on what had gone before.

482 In 1972 when universal screening was introduced.



*“The attitude towards transfusion safety has veered away from the concept of ‘maximum benefit at minimal cost’ towards the notion that if a procedure shown to prevent transfusion-transmitted infection and disease is available, it should be introduced. The latter approach is reinforced by loss of Crown Immunity, the introduction of Product Liability and the emphasis on Quality, Audit and licensing by the MCA.”*<sup>483</sup>

Her general thinking had changed to the idea that if there was a measure that reduced risk it should be taken, despite the fact it might be costly. She was right in this. Mr Justice Burton, in *A v National Blood Authority* formulated it in this way: *“If a precaution shown to prevent, or make a material reduction in, the transfer of transmitted infection through infected blood is available, it should be taken, unless the disadvantages outweigh the advantages.”*<sup>484</sup> The National Blood Authority took the position in that case that cost was not a factor to be taken into account in judging whether there should have been surrogate testing.<sup>485</sup> They were right, too, to do so. Patient safety is paramount.

### **The precautions which could have been taken**

In the absence of a test, however imperfect at the start, which directly identified the virus, the measures available to a blood service in seeking to reduce the amount of infection were as they had been throughout the 32 years of the NHS prior to 1980. They were limited, but important: (1) to select donors carefully, (2) to screen them for environmental and lifestyle factors – and to ask them, as voluntary donors, to exclude themselves if they had infections which suggested they might risk the health of any recipient of their blood. The only other protective step available was (3) avoiding, as far as possible, the use of any transfusion and, if a transfusion was necessary, using no more units than were actually needed.<sup>486</sup>

A second significant part of the context was that what was known was that it often took several months after an infection before it began to manifest itself clearly. The disease was poorly understood by most clinicians. The hallmark of any NANBH infection – raised transaminases on more than one sequential test – could easily be ascribed to obesity or alcohol. Reporting such an outcome to a transfusion centre was unlikely: Dr Dow said in 1987 that 99% of such cases would not be reported.<sup>487</sup> Unless cases were reported, or identified, there would be no easy way of knowing (in the absence of a test) that the person concerned had suffered an infection transmissible by blood.

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483 Medicines Control Agency, which merged into the Medicines and Healthcare products Regulatory Agency (“MHRA”). Professor Dame Marcela Contreras Transcript 3 December 2021 pp116-117 INQY1000166

484 *A v National Blood Authority* Judgment para 106 PRSE0003333

485 *A v National Blood Authority* Judgment para 120 PRSE0003333

486 See the chapters on *Response to Risk by the Blood Services* and *Blood Transfusion: Clinical Practice*

487 Despite his making a point of the very small number of reported cases in the West of Scotland. Gillon et al, Dow et al *Letters to the Editor on Non-A Non-B Hepatitis Surrogate Testing of Blood Donations* The Lancet 13 June 1987 p1 PRSE0002104

Similarly, raised ALT levels in donors might not indicate a disease transmissible to a recipient of their donation. In short, a test of the donor's ALT level would not reliably predict the extent to which disease would follow. On the downside, if such a test showed elevated levels, and the blood was not then used for treatment, this risked discarding harmless donations of blood and the considerable good they might bring to a sick patient.

What was plainly needed was research showing whether raised ALT levels in donors established a greater risk that the transfusion of their blood would cause hepatitis in the recipients of their donations.

Because of the absence of a diagnostic test it could only be estimated, rather than known, what percentage of transfusion recipients suffered hepatitis: an epidemiological study would be needed to bring greater certainty. Estimates were made of the number of recipients who were infected by transfusions. They had to be approached with caution, since they were very much estimates, but in the absence of any greater certainty from a study any policy about blood transfusion screening and practice had necessarily to be based on them. Thus, Dr Gunson, who effectively led the NBTS in the UK in the 1980s, estimated 3% of all recipients of transfusions suffered from post-transfusion NANBH.<sup>488</sup> Although this estimate has been criticised since as being too much on the high side, it was, given its source, the figure against which decisions now fall to be assessed, and it was not out of step with some other estimates at the time.<sup>489</sup>

The consequences of assuming Dr Gunson's figure for incidence can be seen in the calculations which he made.<sup>490</sup> They showed that surrogate testing had the potential to save many cases of illness short of cirrhosis, and several cases of cirrhosis itself. In April 1986, in an article by Koziol and others, much the same analysis was reported in respect of the same disease in the US.<sup>491</sup>

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488 Alanine amino-transferase (ALT) and anti-hepatitis B core (anti-HBc) screening of blood donations October 1986 p13 PRSE0002161, *A v National Blood Authority* Judgment 26 March 2001 para 100 PRSE0003333

489 It is to be noted that in a meeting of SNBTS and haemophilia directors on 9 February 1987 the incidence of post-transfusion NANBH was said to be approximately 2.5% in the UK – a percentage very similar to that adopted by Dr Gunson. Minutes of SNBTS Directors and Haemophilia Directors meeting 9 February 1987 p3 PRSE0002769

490 Alanine amino-transferase (ALT) and anti-hepatitis B core (anti-HBc) screening of blood donations October 1986 p13 PRSE0002161

491 See: Koziol et al *Antibody to Hepatitis B Core Antigen as a Paradoxical Marker for Non-A, Non-B Hepatitis Agents in Donated Blood* *Annals of Internal Medicine* April 1986 p7 PRSE0001533. It pointed out that studies had repeatedly shown that 10-20% of people with chronic hepatitis post transfusion who had been biopsied were shown to have developed cirrhosis. 5% of around three million transfusion recipients per year (in the US) developed NANBH; half of those would have chronic ALT elevation; and at least 10% of those would develop cirrhosis. A reduction of one third (which surrogate testing might provide) "could represent an annual reduction of 50,000 cases of hepatitis and 2,500 cases of cirrhosis." Koziol et al *Antibody to Hepatitis B Core Antigen as a Paradoxical Marker for Non-A, Non-B Hepatitis Agents in Donated Blood* *Annals of Internal Medicine* April 1986 p7 PRSE0001533. Using his similar approach in relation to the UK, Dr Gunson estimated up to 9,000 cases of hepatitis and 900 cases of cirrhosis could be saved. Each year. Though this is the higher end of the range he estimated, on any view the saving of suffering, terminal illness, and associated losses if the tests were to be reasonably effective was very considerable indeed.

It would be an error to tie any analysis too closely to figures such as these, even though they were put forward by Dr Gunson with respect to the UK, and by a distinguished team from the NIH of the US in a peer-reviewed journal:<sup>492</sup> but the thrust of the points made is that the disease – in its chronic phase – was repeatedly shown to be one of significant severity, and that surrogate testing had the potential to reduce its incidence and make a real difference to the lives of many.

### A flawed approach

Applying these principles to the context summarised above, the UK's approach to the question of whether to introduce surrogate screening of blood donations for NANBH was seriously flawed. Responsibility for this lies with both the blood services<sup>493</sup> and with the Government (both the DHSS and the SHHD).

First, patient safety, and the importance of taking measures to reduce the risks of viral transmission, were not proactively considered, as both patient safety and the need for speed required. What stands out from the facts is the chronology of failure to make progress on obtaining desirable data. Thus:

- On 14 February 1980 research was called for to identify the size of the problem in relation to blood transfusions;<sup>494</sup>
- On 25 June 1981 Dr Brian McClelland first presented a proposal for a prospective study;<sup>495</sup> nothing happened;
- On 27 September 1982 it was agreed that Dr Brian McClelland would produce an outline study protocol;<sup>496</sup> nothing happened;
- On 10 January 1983 Dr Brian McClelland produced a paper with an outline proposal (again)<sup>497</sup> – and it was agreed some form of study was needed.<sup>498</sup> Nothing happened;

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492 This note of caution is supported by the Statistics Expert Group's assessment that the incidence of post-transfusion Hepatitis C infections cannot be properly estimated before reliable tests were adopted in the early 1990s. Expert Report to the Infected Blood Inquiry: Statistics September 2022 p58 EXPG0000049. However, the Koziol article was a respectable and easily understandable analysis of the position in 1986 if it is seen not as seeking to provide point accuracy but to convey the broad message that surrogate testing had the potential to provide a meaningful reduction in disease and suffering.

493 I would specifically exempt Dr Brian McClelland from any criticism: he did all he reasonably could to persuade his colleagues. It may also be true that SNBTS were hampered by SHHD's view that they should follow the lead of England on this amongst many health issues affecting the UK as a whole.

494 Minutes of Blood Transfusion Research Committee Working Party on Post-Transfusion Hepatitis meeting 14 February 1980 p2 MRCO0000029\_003

495 Proposal for a Prospective Study of Post Transfusion Hepatitis in the UK 25 June 1981 PRSE0004584

496 Minutes of UK Working Party on Transfusion-Associated Hepatitis meeting 27 September 1982 p2 CBLA0001625

497 Outline Proposal for Prospective Study of Non-A Non-B Hepatitis 10 January 1983 CBLA0001666

498 Minutes of UK Working Party of Transfusion-Associated Hepatitis meeting 18 January 1983 pp2-3 NHBT0000023\_002

- On 25 April 1986 the regional transfusion directors' meeting discussed whether the NBTS should carry out a study; nothing happened;<sup>499</sup>
- In May 1986 Dr Contreras wrote to the DHSS saying that a study of anti-HBc in British blood donors should be undertaken;<sup>500</sup>
- On 4 September 1986 a study was discussed again between Dr Fraser (Bristol) and Dr Cash (Scotland) and on 18 September 1986 Dr Contreras wrote again to the DHSS;<sup>501</sup>
- On 8 October 1986 the regional transfusion directors for England and Wales proposed a prospective study;<sup>502</sup> Dr Gunson wrote a paper to suggest this.<sup>503</sup> No study happened;
- On 24 November 1986 a working party proposed to "*consider a protocol*";<sup>504</sup> and
- By January 1987 what was being considered was now an approach for funding to undertake a study.<sup>505</sup> There was no funding, nor had any study yet begun.

By the time funding was authorised for a multi-centre study,<sup>506</sup> it was known that Chiron Corporation had cloned the Hepatitis C virus and although there remained a place for surrogate testing, the urgency and utility of it was rapidly diminishing.

Extracting these dates from the text shows just how justified Dr Brian McClelland was to speak of "*going round in very small circles some distance away from the target.*"<sup>507</sup> This chronology shows a failure to take timely decisions, either to carry out further research into the effectiveness of surrogate testing or to introduce such testing notwithstanding limitations in the data, in order to prioritise patient safety: the desire to search for more knowledge as a prerequisite for taking precautionary action failed to prioritise patient safety, failed to address the needs of public health with speed, and in searching for more knowledge was the enemy of achieving progress in safety.

There were repeated suggestions that surrogate screening could not be justified in the absence of specific types of further study, accompanied by a failure to undertake such studies, usually on the grounds of time and cost. The debate thus became circular: surrogate screening could not be justified without further study, but the necessary further study could

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499 "After discussion it was agreed that this should not be pursued because of lack of time and resources." Minutes of Regional Transfusion Directors meeting 24-25 April 1986 p7 CBLA0002307

500 Letter from Dr Contreras to Dr Smithies 23 May 1986 NHBT0057025\_001

501 Letter from Dr Fraser to Dr Cash 4 September 1986 PRSE0003936, Letter from Dr Contreras to Dr Smithies 18 September 1986 p1 PRSE0003557

502 Minutes of Regional Transfusion Directors meeting 8 October 1986 pp7-8 CBLA0002345

503 Alanine amino-transferase (ALT) and anti-hepatitis B core (anti-HBc) screening of blood donations October 1986 PRSE0002161

504 Minutes of UK Working Party of Transfusion-Associated Hepatitis meeting 24 November 1986 pp3-4 NHBT0000023\_007

505 The funding application would be submitted four months later. Application for a research grant 28 April 1987 p3 NHBT0000072\_002

506 Letter from R Moore to D Allison 28 April 1988 NHBT0000014\_009

507 Dr Brian McClelland Transcript 28 January 2022 p103 INQY1000178

not itself be justified. The result was a paralysis in decision-making.<sup>508</sup> When a multi-centre study was eventually carried out it was not the prospective controlled study that it had been suggested was required to evaluate the efficacy of surrogate screening. Waiting for its results before deciding whether screening should be introduced is a poor explanation for the delays in decision-making.

There was no clear structure for decision-making. This contributed to the failure to introduce surrogate screening earlier. There is little evidence of proactive involvement and engagement on the part of the DHSS throughout this period. The issue was not raised with or by the Chief Medical Officer, nor was it brought to the attention of ministers. I accept the submission on behalf of the core participants represented by Thompsons Scotland that the disbanding of the MRC Working Party and the apparent failure of the Working Party on Transfusion-Associated Hepatitis to meet more regularly over the period between September 1983 and late 1986 resulted in there being no clear forum in which the important issue of surrogate testing could be discussed and resolved.<sup>509</sup> The lack of clear advisory structures around this time contributed to a lack of proactivity about it. Having a range of different committees does not satisfy the need for one which grasps the nettle, makes decisions, and follows them through: rather than facilitating action, it tends to hide inaction.

Further, as Dr Brian McClelland stated in his Penrose evidence, in the period after these things were “*taken over*” by the need to deal with the AIDS crisis.<sup>510</sup> The opportunity which could have been taken on either of the occasions in the early part of the 1980s was missed. “Decision-making” was to delay actually taking a decision, on the grounds that conducting a study would be costly in terms of time and resource. There was over-reliance on studies such as Dr Dow’s study of cases in the West of Scotland, which was pressed into service as indicating more than it did (it dealt with reported cases, when it ought to have been recognised that this was a very small proportion of a much larger, uncertain total which remained unreported).

Whether to introduce surrogate screening for NANBH in the UK was a complex decision, and the arrival of AIDS undoubtedly diverted attention between 1983 and 1986. However, the complexity of the decision provides little or no justification for a failure to ensure that timely decisions were taken – and implemented – around the need for further study and data collection. Moreover, while the AIDS crisis diverted attention and resources away from NANBH, it should have brought into sharper focus the need to avoid delay in taking decisions in the interest of patient safety, even where those decisions had to be made on the basis of incomplete or limited information.

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508 In his evidence to the Inquiry, Dr Brian McClelland agreed with the description of “*decision paralysis*” when looking at the picture from the early 1980s through to the end of 1988. Dr Brian McClelland Transcript 28 January 2022 pp112-113 INQY1000178

509 Written submissions on behalf of the core participant clients represented by Thompsons Scotland 16 December 2022 pp407-408 SUBS0000064

510 Dr Brian McClelland Penrose Inquiry Transcript 15 November 2011 p89 PRSE0006063



Much of the failure of the Scottish transfusion directors to persuade the SHHD that surrogate testing should be introduced related to the view taken by Dr Forrester. He said, in the second half of the 1980s, that NANBH was “*relatively benign*”.<sup>511</sup> There was no proper basis to say this, other than unjustified assumption. Second, he relied upon the Dow study when he should not have done.<sup>512</sup> This undoubtedly played a part in SHHD resisting calls by regional transfusion directors in Scotland for studies to be funded, and then for surrogate testing to be introduced.

Applying the principle Mr Justice Burton outlined, as set out above, there would have been drawbacks to the introduction of surrogate screening for NANBH. The disadvantages would be most notably the potential impact of introducing screening on the blood supply. This was potentially an issue involving patient safety, if the consequence were to be an insufficient number of transfusions. However, the levels of donors whose donations would have to be discarded were suggested to be around 5% at the highest. Around three times that number within the donor cohort change each year. The loss, even of 5%, seems (albeit impressionistically) unlikely to have been a major problem. Mr Justice Burton who considered the evidence some 20 years before this Inquiry did, and before whom more of the key witnesses were still available, concluded first that there was little to show that any country had suffered problems in the blood supply after the introduction of surrogate screening – certainly, the US did not do so; second, that the donor pool could have been increased by additional efforts;<sup>513</sup> and, third, while the impact on the blood supply would have been a concern, the evidence before him was that it could have been managed.<sup>514</sup> The evidence put to the Inquiry is to similar effect: the blood services cope remarkably well in ensuring sufficient blood supply in almost all circumstances.

The conclusion Mr Justice Burton reached on the issue before him of whether surrogate testing should have been introduced before 1 March 1988 was in these terms:

*“I am clear that the scales have come down in favour of the introduction of these surrogate tests, and indeed of both kinds of surrogate test, both ALT and anti-HBc ... I am clear that ... once ALT testing is to be introduced, the addition of anti-HBc adds little by way of extra disadvantage, cost, blood loss or inconvenience, and may be of substantial advantage. It was, in my judgment, at least very likely to decrease the number of donors who were in any event unwanted, a factor which does not seem to have been discussed at any ACVSB or ACTTD or other meetings to which my attention has been drawn. Further, if the US research was right, the two tests did not, or not materially, overlap, and in any event the combined efficacy of the two together, on the basis of the predictive studies, was*

511 Minutes of SNBTS Directors and Haemophilia Directors meeting 9 February 1987 p3 PRSE0002769, Material for Prime Minister's Office Report 26 January 1987 PRSE0001376

512 Note on transmission of NANBH via blood and blood products 12 June 1986 PRSE0000857, Letter from Dr Forrester to Dr McIntyre 26 March 1986 p2 PRSE0003127

513 As, for instance, the donor response to the Gulf War showed.

514 *A v National Blood Authority* Judgment 26 March 2001 paras 130-131 PRSE0003333

*clearly greater, and there may additionally have been advantages ... in relation to counselling and diagnosis.”*<sup>515</sup>

The evidence to this Inquiry leads to exactly the same conclusion.

The need to counsel those whose blood had tested positive on either test was suggested as a further disadvantage to the potential loss of donors. However, a raised ALT level can have many reasons. Telling a donor that because the ALT level was raised on the occasion they came to give blood is far removed from telling the donor that they have hepatitis. It may be an indication for them to see their GP and discuss with them whether any further test may be needed: but it would not, and should not if carefully and sensitively handled, have caused any significant alarm. Anti-HBc merely indicated that someone had, at some stage, been exposed to Hepatitis B infection and had developed antibodies to it. It is not difficult to ascribe the rejection of a donation which is anti-HBc positive to a policy not to accept blood with those antibodies present – and it is entirely truthful to do so. It is difficult to think that counselling a donor in these terms, in a way appropriate to the donor, would cause any significant problem. If either test led to the detection of an individual who had an active infection, or was a carrier of the virus, then public health would be well served: it would help to reduce the spread or continuation of the virus in the community. The private interest of the infected donor would be better served, too.

Whilst the number of individuals who would have avoided infection with NANBH/Hepatitis C if ALT and/or anti-HBc screening had been introduced cannot now be known, as Dr Gillon put in his statement to the Inquiry: *“there was no doubt that screening with one or both of these tests would prevent some cases of NANBH, and in spite of the lack of data on the incidence of PTNANBH this would be a desirable outcome.”*<sup>516</sup>

Professor Gillon spoke of the position from a Scottish perspective. Dr Gunson, with the perspective of the NBS in England, took a similar line in his evidence to Mr Justice Burton. He summarised it by saying: *“I would like to know the cost of what we are doing, but not necessarily the benefit related to it, because I felt that, if you had to do it, you had to bear the cost.”*<sup>517</sup> He added that he preferred the concept of *“minimum risk”* to *“maximum safety”*, but thought that the view of Drs Barbara and Contreras that *“if a procedure is shown to prevent transfusion-transmitted infection and disease is available, it should be introduced”* had *“probably always [been] the position.”*<sup>518</sup> If that had been so, then it is more difficult to understand why surrogate testing was not introduced earlier. Patient safety should have been the paramount consideration; a procedure was available which potentially could reduce the risk of transfusion-transmitted infection. Cost was inevitable but had to be borne.

In summary, surrogate testing offered the prospect of reducing a serious infection in many patients. Data from the US at the start of the 1980s showed there was a real chance of this.

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515 *A v National Blood Authority* Judgment 26 March 2001 para 141 PRSE0003333

516 Written Statement of Professor Jack Gillon para 178 WITN6987001

517 *A v National Blood Authority* Judgment 26 March 2001 para 104 PRSE0003333

518 *A v National Blood Authority* Judgment 26 March 2001 para 104 PRSE0003333

But it had not proved that testing would be effective. It was right, therefore, to look for further data particular to the UK. The prevalence of NANBH in the UK population might be very different from that in the US, just as was the case with Hepatitis B. However, given the context, too long should not have been taken on this step. Unfortunately, it was.<sup>519</sup> There was a failure by the DHSS to provide the opportunity and the resourcing of the appropriate study. If that information was not going to be forthcoming, then a decision could and should have been made on the material that was then available.

In his evidence to Mr Justice Burton, Dr Gunson was asked about this in the last question and answer of his cross-examination: “Q: *if one put cost to one side, all the material from wherever you looked ... showed that the introduction of ALT screening would have a beneficial effect if one looked at the concept of minimal risk for the recipient. All the material was to that effect, was it not?* A: *Yes, it would reduce the risk to the recipient.*”<sup>520</sup> It follows that on the basis of the information then available, in the absence of more informative data telling against it, the decision should then have been taken to introduce surrogate testing.

In light of all that I have set out above, surrogate testing could and should have been introduced in the UK in the first half of the 1980s. This case is all the stronger when the evidence discussed in the following chapter on HIV surrogate screening is considered, for if anti-HBc testing of donations had been introduced in an attempt to combat the scourge of AIDS by acting as a surrogate test for HIV it would also have functioned as a partial surrogate screen for NANBH. The case for it became even more clear-cut following the publication by Drs Alter and Dienstag in early 1986. It was this which led to the US introduction of such screening. There is no proper justification for the failure thereafter to introduce surrogate testing in the UK no later than January 1987, and probably by mid 1986.

Would it have made a difference? The answer is, probably, yes.<sup>521</sup> Although the numbers cannot be known, there is powerful material to show that surrogate testing would probably have saved a number of infections from being caused by transfusion. Thus, in November 1989 Alter et al wrote in the *New England Journal of Medicine* that “‘Surrogate’ assays for anti-HBc and alanine aminotransferase would have detected approximately half the anti-HCV-positive donors involved in the transmission of hepatitis that we identified.”<sup>522</sup>

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519 Professor Contreras confirmed in her evidence that she too considered it to have taken too long. Professor Dame Marcela Contreras Transcript 3 December 2021 p61 INQY1000166

520 Court transcript of cross-examination of Dr Harold Gunson in *A v National Blood Authority* 26 October 2000 p89 NHBT0000148\_001

521 SNBTS have on balance reached the conclusion that surrogate testing should have been introduced. In their submission to the Inquiry it is said: “*We feel that on balance, in the absence of [adequately powered prospective clinical studies] and with the emergence of the long-term effects of HCV infection in some patients, surrogate testing should have been introduced in Scotland as a precautionary measure ... it was not possible for SNBTS to introduce such testing without external funding and UK Government support. In reaching this conclusion we acknowledge that the data is complex and caveated.*” Written submission of National Services Scotland and SNBTS para 113 SUBS0000044. The absence of “*adequately powered prospective clinical studies*” was a “*missed opportunity*”. Written submission of National Services Scotland and SNBTS para 105 SUBS0000044

522 Alter et al *Detection of Antibody to Hepatitis C Virus in Prospectively Followed Transfusion Recipients With Acute and Chronic Non-A, Non-B Hepatitis* *New England Journal of Medicine* 30 November 1989 p1 OXUH0000022\_002

Dr Alter – this time in a textbook chapter written with another co-author in 1998 – repeated this early view: nothing had happened in the intervening period to invalidate it.<sup>523</sup> That, of course, was looking at the position in the US. There was some discussion whether the same would hold good in the UK. A separate study in Canada, reported in *The Lancet*, found that 70% of Hepatitis C infections would have been avoided by the use of the two surrogate markers, ALT and anti-HBc.<sup>524</sup> In his evidence to the Inquiry, Professor Barbara said “*if you had taken appropriate cut-offs for ALT and anti-core and excluded donors who were both – only excluded donors who were both anti-HCV pos and ALT raised – you were approaching the predictive value of real infectivity as you did with the first generation anti-HCV ELISAs [enzyme-linked immunosorbent assays].*”<sup>525</sup> He was, of course, speaking of the UK. But the position seems to be the same as in the US.

In assessing whether or not surrogate testing should have been introduced, this retrospective evidence that it would most probably have been effective cannot be taken into account – those making the decisions did not know it at the time. But they knew there was a large risk from NANBH, and they knew there was a really good chance that surrogate testing would help to reduce it, and they did not introduce it.

This was a failure.

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523 Alter and Seeff *Transfusion-Associated Hepatitis Clinical Aspects of Viral Liver Disease* p7 NHBT0000117\_047

524 Blajchman et al *Post-transfusion hepatitis: impact of non-A non-B hepatitis surrogate tests* *The Lancet* 7 January 1995 p1 PRSE0004703

525 Professor John Barbara Transcript 26 January 2022 pp93-94 INQY1000176. In short, this is saying that surrogate tests would be almost as good as the first generation of tests directly for Hepatitis C.

## 5.3 HIV Surrogate Screening

Prior to the identification of the AIDS virus, it was not possible to test donations directly. This chapter looks at decision-making regarding the use of anti-HBc tests as a means of identifying high risk donors, so that donations from them did not enter the blood supply, and assesses the speed and adequacy of that decision-making

### Key dates

**12 May 1983** Dr Craske writes to Dr Barbara that he does not favour the use of anti-HBc screening.

**22 September 1983** regional transfusion directors' meeting notes that the most risky populations may be identifiable by anti-HBc markers; no further discussion.

**27 September 1983** Dr Barbara observes at a working party meeting that the anti-HBc test has the value of association with Hepatitis B and NANBH as well as AIDS.

**14 October 1983** CBLA Working Group on AIDS discusses surrogate screening and asks Dr Brian McClelland to submit outline proposals for prospective study.

**27 January 1984** CBLA Working Group on AIDS agrees that a protocol for a study should be drawn up.

**28 February 1984** Dr Wallington presents protocol for study on surrogate screening at the CBLA Central Committee for Research and Development in Blood Transfusion.

**17 April 1984** application made for funding from MRC for the prospective study

**Summer 1984** direct testing for HTLV-3 thought to be in the offing.

**14 October 1985** universal screening of blood donations for HIV commences in the UK.

### People

**Dr John Barbara** North London Blood Transfusion Centre

**Dr John Craske** Public Health Laboratory Service

**Dr Brian McClelland** Scottish National Blood Transfusion Service

**Dr Tim Wallington** Bristol Regional Transfusion Centre

### Abbreviations

**anti-HBc** Hepatitis B Core Antibody

**CBLA** Central Blood Laboratories Authorities

**DCMO** Deputy Chief Medical Officer

**DHSS** Department of Health and Social Security

**MRC** Medical Research Council

**PHLS** Public Health Laboratory Service



## Should there have been surrogate screening for HIV?

The US Committee to Study HIV Transmission Through Blood and Blood Products, established in 1993 by the Institute of Medicine at the request of the US Department of Health and Human Services, considered whether surrogate testing for Hepatitis B core antibody (“anti-HBc”) could and should have been amongst the measures taken to screen donors in order to reduce the risk of AIDS. It concluded that asking male donors about sexual activity with other men and screening donated blood for the anti-HBc antibody would have been “*reasonable to require*” in January 1983.<sup>526</sup>

The Haemophilia Society, in its closing submissions to the Inquiry through its solicitors, registered its agreement with this conclusion.<sup>527</sup> Thompsons Solicitors, representing many of those infected and affected in Scotland, submitted that some infections in Scotland “*might have been prevented by better donor selection measures or the introduction of surrogate testing for HIV amongst donors, either of immune function or anti-HBc, neither of which were routinely used*”.<sup>528</sup>

Until the virus responsible for AIDS had been identified, there was no possibility of testing donations directly to see if they might be infected with a causative virus, and if they were found positive, to reject using them to treat patients. The only defences were (1) in the way treatment was given: not giving a transfusion (or blood product) if that could be avoided, and ensuring that no more units of blood were transfused (or no more blood product was given) than strictly necessary; and (2) in the way blood was collected for use, by (a) selecting donors from groups less likely to be harbouring any such virus, and (b) screening donors, usually by giving prior advice as to their suitability as donors, by questionnaires, by questioning at the point of donation, and (possibly) by applying a test indicating that the donor’s blood posed too high a risk for their donation to be accepted. Whether and to what

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526 Institute of Medicine Committee to Study HIV Transmission Through Blood and Blood Products *HIV and the Blood Supply: An analysis of crisis decisionmaking* 1995 p136 JREE000019. The Committee considered that public health authorities in the US had rejected these because (a) lack of consensus about costs and benefits of screening and deferral resulted in decisions that took a limited approach to issues of donor safety, and (b) political, organisational, and historical constraints in the environment prevented decision makers from implementing screening for high-risk sexual practices and for anti-HBc. Institute of Medicine Committee to Study HIV Transmission Through Blood and Blood Products *HIV and the Blood Supply: An analysis of crisis decisionmaking* 1995 pp136-137 JREE000019. These included lobbying by gay groups, plasma fractionators, and blood banks each promoting their cases whilst the cause of AIDS remained a matter of some dispute in the scientific community, coupled with a general reluctance on the part of the US Administration “*to treat AIDS as an urgent and serious public health threat ... there was little potential political reward, and some political cost, associated with taking a leadership position in AIDS prevention, especially one that attracted political opposition from vocal and powerful groups that could argue that proposed actions were not required by scientific information.*” Institute of Medicine Committee to Study HIV Transmission Through Blood and Blood Products *HIV and the Blood Supply: An analysis of crisis decisionmaking* 1995 pp126-136, p139 JREE000019. It is acknowledged that the US and other nations did not introduce such testing but just as the Institute of Medicine Committee was considering what should have been done, so too should the UK.

527 Submission of the Haemophilia Society pp175-176 16 December 2022 SUBS0000065

528 Submission of Thompsons Solicitors Scotland p364 16 December 2022 SUBS0000064

extent such a “surrogate” test was considered at all in the UK, and whether it should have been introduced, is the subject of this chapter.<sup>529</sup>

Dr John Craske of the Public Health Laboratory Service was aware in the spring of 1983 of the possibility that anti-HBc screening might reduce the risk of what was then thought to be a virus transmissible by blood. He wrote to microbiologist Dr (later Professor) John Barbara at the North London Blood Transfusion Centre to say he did not favour the test: given the long incubation period before symptoms of AIDS emerged, it was doubtful whether testing for anti-HBc would detect some patients early enough in the stage of their disease to remove the risk of transmission of infection by transfusion.<sup>530</sup>

Dr Barbara did not and does not entirely accept Dr Craske’s view:

*“I did not agree entirely with his comment on anti-HBc screening. I felt that screening blood for HBc antibody would help to detect transmission of AIDS. HIV was transmitted by homosexual intercourse and by intravenous drug use. Those were the two key, natural ways of transmission and of course, that’s how hepatitis B can be transmitted. Therefore, testing for evidence of hepatitis B transmission at some point may have correlated with the risk of HIV transmission. We used to say, these viruses ‘hunt in packs’ and so it could correlate with the risks of co-infection ... Testing for anti-HBc would give some evidence of a past hepatitis B infection. Anti-HBc positivity might reflect a shared route of infection by HBV or HIV. However, HBV would also commonly be transmitted at birth or shortly after.”<sup>531</sup>*

Dr Barbara’s observation correctly identifies the logical flaw in Dr Craske’s reasoning. The purpose of testing for anti-HBc was not to detect the presence of the virus causing AIDS: it was to detect those who may have previously had Hepatitis B, given the possible shared routes of infection.<sup>532</sup>

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529 Transfusion practice is considered in the chapter on *Blood Transfusion: Clinical Practice*; treatment with blood products in the chapter on *Haemophilia Centres: Policies and Practice*; and donor screening and selection in the chapter on *Response to Risk by the Blood Services*.

530 Letter from Dr Craske to Dr Barbara 12 May 1983 NHBT0017448\_004

531 Written Statement of Professor John Barbara paras 308-309 WITN6989001

532 It is for this reason that questions of whether a surrogate test would be sufficiently specific are beside the point – the purpose of it was essentially to better identify those who were in a group the members of which were at higher risk of harbouring the virus which presumptively was the cause of AIDS, so that their donations could then be excluded from onward transmission. There was a risk that if there was a large number of false positive results, a large number of donors would be identified by a surrogate test as being a high risk, and would wrongly be lost to the system. However, since the strong likelihood is that a direct test for HIV would emerge before long, surrogate screening was always likely to be a time-limited response, to a very serious risk of incurring a potentially deadly disease for which there was as yet no known cure (as materialised in all too many cases, including people infected from blood products made from pooled donations and whole families infected as a result of one family member’s transfusion). Deferring donations from some donors could have been sensitively managed, and though the existence of false positives was a factor to be borne in mind, the challenge of false positives was not a barrier to introducing surrogate screening.

Though he was doubtful of the value of anti-HBc screening, Dr Craske nonetheless thought it merited discussion *“at an early meeting, or possibly at a special Working Party which I know [Dr] Harold Gunson has in mind to initiate to look into this question.”*<sup>533</sup>

There was no consideration of this question at the next meeting of regional transfusion directors on 18 May 1983,<sup>534</sup> though it appears that the first meeting of the Central Blood Laboratories Authority (“CBLA”)’s Central Committee for Research and Development in Blood Transfusion on 21 June 1983 did discuss in some detail ways of dealing with the problems of AIDS for the blood supply. The minutes record that not enough was known about AIDS to enable any decisions to be made. It is unclear whether any of the discussion focused on the possibilities of surrogate testing.<sup>535</sup>

The meeting of regional transfusion directors on 22 September 1983 noted that: *“No tests for AIDS were available but early information suggested that the most risky populations, namely promiscuous homosexuals, may be distinguished by possession of positive results for hepatitis B core antibody (possibly the most valuable marker) hepatitis B surface antigen and antibody and TPHA syphilis tests.”* There was, however, no further discussion of the issue at that meeting.<sup>536</sup>

Dr Barbara, at a meeting of the UK Working Party on Transfusion-Associated Hepatitis on 27 September 1983, was recorded as commenting that the anti-HBc test *“had the value of association with hepatitis B and non-A, non-B hepatitis as well as AIDS.”*<sup>537</sup>

A Working Group on AIDS, set up by the CBLA as an ad hoc working group *“to consider the problem of AIDS in relation to the transfusion of blood and blood products”*, had its first meeting in October 1983 and one of the topics was surrogate testing.<sup>538</sup> The proportion of donations which might be excluded by a positive test was indicated by the percentage of samples obtained in Bristol which tested positive, which was 0.75% (75 cases out of 10,000 tests).<sup>539</sup> In North London it was 2.6% (after screening 25,000 samples). This showed that different areas might vary considerably in the incidence of positive anti-HBc test results. The outcome was that Dr Brian McClelland, the director of the Edinburgh and South East Scotland Blood Transfusion Service, agreed to collate the information that had already been obtained on anti-HBc screening and to submit outline proposals for a prospective study

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533 Letter from Dr Craske to Dr Barbara 12 May 1983 p2 NHBT0017448\_004

534 Minutes of Regional Transfusion Directors meeting 18 May 1983 CBLA0001707

535 Dr Brian McClelland *“outlined ways of dealing with the problem from various aspects”*, which were apparently *“discussed in some detail”*. The minutes do not record what those suggestions were: the *“general feeling seemed to be that although several ideas were worth considering not enough was known about AIDS to enable any decisions to be made.”* Minutes of CBLA Central Committee for Research and Development in Blood Transfusion meeting 21 June 1983 p2 PRSE0002741

536 Minutes of Regional Transfusion Directors meeting 22 September 1983 p3 CBLA0001742

537 Minutes of UK Working Party on Transfusion Associated Hepatitis meeting 27 September 1983 p4 PRSE0001299

538 Minutes of CBLA Working Group on AIDS meeting 14 October 1983 pp2-3 CBLA0001754

539 It emerged that 48 out of these 75 were prisoners, so at a meeting on 7 November 1983 it was decided that Bristol would test another 10,000 donations prospectively, this time excluding prisoners’ donations. Minutes of CBLA Central Committee for Research and Development in Blood Transfusion meeting 7 November 1983 p3 SCGV0000052\_086

in time for the next meeting early in 1984. The note of the meeting then continues: “*The Chairman stressed that economical considerations could not be ignored if it was concluded that an additional test for screening blood donors was proposed.*”<sup>540</sup>

At the next meeting of the CBLA Central Committee for Research and Development in Blood Transfusion (under whose auspices the Working Group on AIDS had been established), on 7 November 1983, the Committee “*welcomed the action taken with respect to the investigation of the use of surrogate tests*” and looked forward to Dr McClelland’s report.<sup>541</sup>

Thus it can be seen that the proposed study, rather than the actual introduction of surrogate testing, took centre stage.

At this point, the World Health Organization produced a draft report. It accepted that a test, indirectly related to particular risk groups, could theoretically help to identify individuals who were at risk of AIDS, and who thus should not be accepted as donors: but the particular environment in which it was to be applied had to be considered, “*taking into consideration [the] potential effectiveness of the test as well as the impact on the blood supply and the potential alienation of donors.*”<sup>542</sup>

By January 1984, Dr McClelland had prepared a discussion paper.<sup>543</sup> After considerable discussion on 27 January, when the CBLA Working Group on AIDS met for the second time, it was agreed that “*If studies involving additional tests to the ones currently being carried out in Bristol and Edgware were carried out, the question of resources would need to be considered and therefore the CBLA through the Central Committee for R&D [Research and Development] would have to make a decision on the viability of this. It was also felt that an approach to the MRC [Medical Research Council] might be appropriate.*”<sup>544</sup>

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540 Dr Harold Gunson was the chairman. Minutes of CBLA Working Group on AIDS meeting 14 October 1983 p3 CBLA0001754. At the meeting of the Advisory Committee on the National Blood Transfusion Service on 17 October 1983, the understanding of what had been decided by the Working Group on AIDS was that “*a survey of two studies, at Bristol and North London, was to be carried out.*” Minutes of National Blood Transfusion Service Advisory Committee meeting 17 October 1983 pp4-5 CBLA0001763

541 Minutes of CBLA Central Committee for Research and Development in Blood Transfusion meeting 7 November 1983 p3 CBLA0001766. According to a note prepared by Dr Albert Bell of the Scottish Home and Health Department, who attended the meeting on 7 November 1983, Dr McClelland commented on the inefficiency of anti-HBc screening, since it identified a sociological group rather than an infected cohort. However, Dr Bell recorded also that the meeting noted that it was the “*only screen seriously considered*”, since “*others ... were not at present sufficiently promising.*” Minutes of CBLA Central Committee for Research and Development in Blood Transfusion meeting 7 November 1983 p3 SCGV0000052\_086

542 Draft World Health Organization report *Acquired Immunodeficiency Syndrome, an assessment of the present situation in the world* 12 December 1983 p19 CBLA0001775. It included the wording: “*Since such tests are not direct measures of AIDS or of susceptibility to AIDS, a certain number of individuals not belonging to a risk group would be excluded from donating blood. This number may vary considerably in different parts of the world, depending upon the characteristics of the risk groups. Thus, the specificity and sensitivity of any such test(s) for this purpose must be evaluated in the environment in which it is to be applied.*”

543 Note for CBLA Research Committee AIDS Working Party 27 January 1984 NHBT0087432\_003

544 Minutes of CBLA Working Group on AIDS meeting 27 January 1984 p2 DHSC6887728\_142



It was agreed that a protocol for a study, including the probable cost implications, would be drawn up for the next meeting of the CBLA Central Committee for Research and Development in Blood Transfusion which took place on 28 February 1984.<sup>545</sup> This was put together by Dr Tim Wallington (Bristol), who presented it to the meeting.<sup>546</sup> It proposed that a total of 50,000 donors across two centres<sup>547</sup> would be screened, and those testing positive would be followed up to see what correlation there was with those falling in “*high-risk*” groups for AIDS. It was agreed that the proposal should be written in the form of a grant application to the Medical Research Council (“MRC”), although the Committee was informed that the MRC “*was in the position of having to turn down acceptable projects on AIDS because funds were over-stretched*”. It seems to have been hoped that a study such as this would be regarded as appropriate for MRC funding “*under health services research*” and the Committee requested the CBLA and the Department of Health and Social Security (“DHSS”) to support the proposal and communicate that support to the MRC.<sup>548</sup>

A note of the meeting taken by Dr Albert Bell of the Scottish Home and Health Department (“SHHD”) is interestingly informative: “*I sensed that there was not great enthusiasm in the Committee for this particular study but rather a feeling that since some steps had to be taken to identify potential transmitters of AIDS other than reliance on individual donors opting out themselves, an exercise of this kind had to be undertaken and no one could produce a better protocol.*”<sup>549</sup>

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545 Minutes of CBLA Central Committee for Research and Development in Blood Transfusion meeting 28 February 1984 PRSE0001972. Dr Alison Smithies’ note following the meeting is at: Letter from Dr Smithies to Dr Mary Sibellas 2 March 1984 DHSC0002321\_040

546 On 16 February 1984 Dr McClelland wrote to Dr John Cash expressing concerns about the process. Letter from Dr McClelland to Dr Cash 16 February 1984 SBTS0001264\_001. He had met Dr Wallington, Dr (later Professor) Richard Tedder, Dr (later Professor) Marcela Contreras, Dr Barbara and others on 15 February 1984 to discuss the proposal but “*had a number of quite serious reservations about the way they conceive the study*”. The outcome had been that Dr Wallington would prepare for the CBLA meeting an outline proposal for a study which would be initially conducted from Edgware and Bristol. The document which was discussed at the meeting on 15 February 1984 recognised that anti-HBc “*is present in [sic] most patients with A.I.D.S., A.I.D.S. related syndromes and members of ‘at risk’ groups particularly homosexuals and intravenous drug abusers.*” Donor Screening Using Non-Specific Tests to Recognise High Risk Groups p2 SBTS0001266\_001. The final version presented by Dr Wallington at the meeting on 28 February: The Acquired Immunodeficiency Syndrome (AIDS): Can laboratory screening tests identify blood donors at high risk of transmitting AIDS? CBLA0001973

547 Bristol and Edgware (North London Blood Centre).

548 Minutes of CBLA Central Committee for Research and Development in Blood Transfusion meeting 28 February 1984 PRSE0001972. Dr Smithies, in her note following the meeting, explained that “*When asked I said that the Department [of Health] would be very happy to look at the proposal but similar constraints to those at the MRC (i.e funds) would apply.*” Letter from Dr Smithies to Dr Mary Sibellas 2 March 1984 DHSC0002321\_040

549 Note of CBLA Central Committee for Research and Development in Blood Transfusion meeting 28 February 1984 p2 SCGV0000052\_073. It seems to represent a “something must be done, so we may as well try this” approach. The epidemic was growing. It should be noted that the study now proposed by Dr Wallington was smaller in scale than he had originally envisaged because of limited supplies of the necessary reagent (it targeted 50,000 tests, to be applied at two transfusion centres only, and would require some medical follow-up for those identified as members of an at-risk group, which he recognised might be contentious). It was thus “*not quite the study*” first envisaged. Nonetheless, Dr Wallington said “*I hope that we will be able to pursue these studies. I am sure that we will be able to answer important questions if we do.*” Letter from Dr Wallington to Dr Gunson 23 February 1984 NHBT0004229. This may have lessened enthusiasm for the project as a whole, but the decision was still to support it.



At a meeting on the infectious hazards of blood products which had taken place earlier that month (on 9 February 1984) attendees (including Dr Richard Lane and Dr Duncan Thomas, both of whom were also on the CBLA Committee for Research and Development in Blood Transfusion) had heard Dr John Petricianni of the Food and Drug Administration state, in relation to the US experience, that “*anti-hepatitis B core antibody is positive in more than 90 per cent of AIDS cases*”.<sup>550</sup>

On 17 April 1984 an application for support from the MRC was duly advanced. It noted that:

*“Although the cause of AIDS is unknown its epidemiology suggests strongly that an infectious agent is responsible ... Transmission is by blood, blood products, blood contaminated instruments and sexual intercourse particularly anal intercourse, a situation very reminiscent of Hepatitis B a serious problem in blood transfusion before screening tests were introduced. These routes of infection largely confine AIDS to persons whose life style puts them at high risk, (high risk groups, homosexual/bisexuals, intravenous drug abusers, haemophiliacs [sic]) these include recipients of blood and products if persons with AIDS are accepted as blood donors.”*<sup>551</sup>

The proposal sought to see if anti-HBc positive tests were indicative of membership of one or more of the “*at risk*” groups. However, the proposal was for a study taking two years, which would not begin until November 1984.<sup>552</sup>

The MRC’s Working Party on AIDS met on 17 April 1984, but did not discuss the application. There was some awareness, however, that an application was in the pipeline, as the MRC Working Party noted the minutes of CBLA’s Working Group and observed: “*The point was raised that the CBLA itself had no funds, but needed to seek scientific solutions to rather pragmatic questions, such as those of surrogate tests. The Working Party considered how such projects should be handled, and it was thought quite appropriate that applications should be submitted in the normal way to the MRC and/or DHSS.*”<sup>553</sup>

Two days later Dr Harold Gunson, in his role heading up the Blood Transfusion Service, sent the funding application to the Deputy Chief Medical Officer (“DCMO”) Dr Edmund Harris,<sup>554</sup> commenting:

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550 He added that it was “*also positive in approximately five per cent of normal individuals.*” The note of the meeting at the National Institute for Biological Standards and Control (“NIBSC”) recorded that there was general agreement, on the present evidence, that only the test for Hepatitis B core antibody was thought likely to be of value, but that “*there was no general agreement that such testing for core antibody should be part of the routine screening carried out on all donors.*” It is not possible to tell from the note which attendees supported the introduction of anti-HBc screening and which did not. Minutes of NIBSC Infectious Hazards of Blood Products meeting 9 February 1984 p4, p10 PRSE0003071

551 Letter from Dr Wallington to R Smart 17 April 1984 p4 CBLA0001837

552 Letter from Dr Wallington to R Smart 17 April 1984 p2 CBLA0001837

553 Minutes of Medical Research Council Working Party on AIDS meeting 17 April 1984 p5 MRCO0000541\_061

554 DHSS officials knew of the matters that had been discussed at a number of the groups, for they were in attendance at those meetings. In particular, this applies to the CBLA Central Committee for R&D in Blood Transfusion, Working Group on AIDS, and the Advisory Committee on the National Blood Transfusion Service, chaired as it was by the DCMO. Dr Gunson, as this letter shows, was in contact

*“I think that it is very important that this study is put into operation since I fear that we may otherwise be forced into anti-HBc screening by events taking place in the U.S.A. ... Implications for the introduction of such screening throughout the Country are considerable; the cost of reagents alone would add £1M to the Transfusion Service revenue and in addition there would be the requirement for additional staff and in some R.T.C.’s [sic] additional space.”*<sup>555</sup>

He acknowledged, however, that *“it must be said”* that the proposed study *“may give an indication that certain persons in high risk groups can be identified in a manner other than self-selection.”*

By the summer of 1984, screening tests for HTLV-3/HIV were in the offing, though there was as yet no date for their universal adoption across the UK (nor even a decision that they would be adopted). At a meeting of the CBLA on 23 May 1984 Dr Gunson suggested that the application to the MRC, from whom a decision was awaited, *“had now been somewhat overtaken by events”* and that he and Dr Wallington were *“preparing a paper modifying proposals in regard to the grant application”*.<sup>556</sup>

The MRC Working Party on AIDS met next on 25 October 1984, where it was recorded that the number of cases of AIDS in the UK was continuing to rise sharply. There was no further discussion of the issue of anti-HBc screening, and no decision as to whether it should or should not be introduced as a surrogate test for HIV was ever taken.<sup>557</sup>

What hampered the adoption of anti-HBc as a surrogate test was summed up by Dr Barbara and Dr (later Professor) Richard Tedder writing in October 1984: *“In our experience at NLBTC [North London Blood Transfusion Centre], evidence of previous HBV infection identifies donors at a significantly higher risk of transmitting NANB and at a marginally higher risk of transmitting HBV. At present it is not known whether this would be a suitable or effective screen for donors who constitute a high-risk of transmission of AIDS.”*<sup>558</sup> It was the lack of knowledge – a lack which the proposed study would have addressed. By the summer of 1984 there was also no doubt a belief that a direct screening test would become available

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with Dr Harris to seek wider help. The SHHD were aware, too, of the issue of surrogate screening – see for instance the involvement of Dr Bell as mentioned in the text.

- 555 Letter from Dr Gunson to Dr Harris 19 April 1984 DHSC0002241\_017. His concern about being bounced into expense and inconvenience by developments in the US was confirmed in his view when, on the same day, he circulated an American Association of Blood Banks’ newsletter including discussions about anti-HBc testing, on the basis of which he commented *“it seems that our efforts in this direction are timely.”* Letter from Dr Gunson to members of the Central Research Committee AIDS Working Party 19 April 1984 p1 CBLA0001838
- 556 Minutes of Central Blood Laboratories Authority meeting 23 May 1984 p3 CBLA0004998. On 3 July 1984 Dr Gunson reported to Dr Smithies that he had met with Dr David Tyrrell, Dr Tedder, Dr Wallington and Dr Contreras to consider a study on blood donors using the detection of anti-HTLV-3 as a possible marker for donors who might be at high risk of transmitting AIDS. Letter from Dr Gunson to Dr Smithies 3 July 1984 p1 PRSE0003901
- 557 Minutes of Medical Research Council Working Party on AIDS meeting 25 October 1984 p2 MRCO0000541\_047
- 558 Barbara and Tedder *Viral Infections Transmitted by Blood and Its Products* Clinics in Haematology No3 October 1984 p12 NHBT0000030\_009

in the near future. In fact, it was not until 14 October 1985 that universal screening of blood donations for HIV commenced in the UK.

## Commentary

Very broadly put, US cases of AIDS arose around 18 months ahead of such cases in the UK. Blood products to treat people with haemophilia in the US were made from plasma which was bought from “donors”, a substantial number of whom would not have been accepted as donors in the UK – and most of that “substantial number” would not have offered their blood for therapeutic use if they had been in the UK and had been asked to provide their blood freely, as a true donation. The prevalence of Hepatitis B, and of non-A non-B Hepatitis (“NANBH”) was higher, too. Thus the risks to a recipient of a blood product or donation were even greater than in the UK, and the need to do something to reduce them correspondingly must have seemed more urgent still.

It follows that the arguments for the introduction of anti-HBc testing thus probably would be seen as being stronger in the US than in the UK – but also that the UK had an opportunity to learn from the US experience given that the US was probably 18 months or so ahead.

There are three disappointing aspects of the factual account set out above. First, there was a lack of urgency when it came to patient safety. If more information was needed, it should have been more rapidly obtained. Yet, despite the fact that the potential for transmission by blood and blood products had become apparent in the course of 1982, the issue was not even considered until October 1983, at which point no decision was taken save to ask Dr McClelland to submit outline proposals for a prospective study; the protocol for such a study was only considered in late February 1984; there was as yet no funding in place for the study (still less for the screening if introduced); and the application that was submitted in April 1984 to the MRC was for a study which would not conclude until November 1986. In the teeth of an impending epidemic, as the US experience strongly suggested, this was far too wasteful of time.

Second, no-one seems in the course of argument clearly to have linked surrogate screening for HIV and for NANBH<sup>559</sup>. Anti-HBc positivity was potentially indicative in both. This consideration, if carefully pondered, might have made a difference in its introduction – and for that matter, have accelerated the date by which the introduction of surrogate screening for NANBH should have been achieved.

Third, no one grasped the nettle and actually sought to take a decision about the introduction of anti-HBc screening, even though it was acknowledged as the only real surrogate test of likely value and was a test which, clearly, it would not have been unreasonable to introduce. Whilst there was in the UK, as in the US, a lack of consensus about the costs and benefits, recognition of the need to avoid high-risk donors fell short when it came to taking practical steps. While donor leaflets had been introduced generally in September

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<sup>559</sup> Dr Barbara did mention it, though his contribution is recorded in somewhat oblique terms. Minutes of UK Working Party on Transfusion Associated Hepatitis meeting 27 September 1983 p4 PRSE0001299

1983, they progressively needed tightening over the next four years,<sup>560</sup> and were never likely to dissuade all high-risk donors, and direct screening for HIV was not introduced until October 1985. The anti-HBc test would thus have provided a further way of avoiding high-risk donors. Given that the policy accepted in drafting the leaflets was to prevent donations from high-risk donors, such as those who were likely to be identified by anti-HBc testing, a surrogate screening test would more surely have achieved it. Responsibility for this missed opportunity rests with the Government (DHSS and the Scottish Home and Health Department, but primarily the former) and the blood services.

Almost the last word on this I leave to Professor Barbara. He said:

*“we are looking at anti-HBc in the context of a phrase that virologists use about viruses running in packs, a common source of infection for various agents, like intravenous drug use. And my feeling was that there was some possible merit, certainly worth considering, of anti-HBc as an indication of past or present infection with an agent that could, as it were, co-infect with HIV ... It could have been a useful -- I don't think I ever formulated it in my own head as something that I would definitely want to press ahead with but it was an idea, it was a concept that might have some utility.”*<sup>561</sup>

This answers the question – if anti-HBc screening had been introduced, might it have been useful (which means potentially saving lives) – with the word “yes”.

What the facts show is that there was, on any view, a missed opportunity because of a lack of urgency. Had the nettle been grasped, and patient safety been sufficiently prioritised as it should have been, a decision would have been taken, probably in 1983 to introduce anti-HBc screening.

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560 The language used is listed in: Expert Report to the Infected Blood Inquiry: Statistics September 2022 p38 EXPG0000049. See the chapters on *Response to Risk by the Blood Services* and on *Role of Government: Response to Risk* for further discussion of the AIDS leaflet.

561 Professor John Barbara Transcript 26 January 2022 pp40-42 INQY1000176

## 5.4 HIV Screening

This chapter considers why blood donations in the UK were not screened for AIDS until October 1985. It examines the decision-making process regarding the introduction of screening, and whether such screening should have been introduced more quickly than it was.

### Key dates

**23 April 1984** Dr Robert Gallo announces that he has identified the virus causing AIDS.

**10 July 1984** DHSS minute says screening test must be introduced “as quickly as possible”.

**31 August 1984** *The Guardian* announces a UK test has been developed.

**1 September 1984** *The Lancet* reports that 34% of people with haemophilia who had been tested, having received pooled clotting factors, had tested positive.

**27 November 1984** first meeting of working group on AIDS says tests must be used for all donors “as soon as possible”.

**December 1984** media reveals that an HIV positive donor in the UK had given blood which had transmitted the virus to three others; public statement by CMO.

**January 1985** ministers asked to agree in principle use of screening test; agreed.

**16 January 1985** Letter from Professor Bloom to the DHSS in support of testing.

**16 January 1985** Decision that available screening tests need to be evaluated before being used.

**29 January 1985** first meeting of EAGA discusses screening test.

**15 March 1985** DHSS tells regional transfusion directors that it is in the interests of the blood services to delay testing until tests have been properly evaluated.

**May 1985** routine screening for HIV antibodies commences in several countries; in the UK the evaluation of the tests has still not commenced.

**30 May 1985** John Patten questions the CMO on the timescale for introducing testing.

**31 May 1985** Professor Bloom writes to the DCMO to reinforce the need for the rapid introduction of a screening test.

**27 June 1985** Kenneth Clarke announces a test will be introduced within months.

**30 July 1985** PHLS recommends three tests to EAGA.

**14 October 1985** screening of all donated blood begins in the UK.

### Key people

**Professor Arthur Bloom** chair, UK Haemophilia Centre Directors’ Organisation

**Kenneth Clarke** Minister of State for Health (1982 - 1985)

**Dr Brian McClelland** Scottish National Blood Transfusion Service

**John Patten** Parliamentary Under-Secretary of State for Health (1983 - 1985)

**Dr Alison Smithies** principal medical officer, Department of Health and Social Security

**Dr Richard Tedder** virologist, Middlesex Hospital

**Professor Robin Weiss** director, Institute of Cancer Research

### Abbreviations

**EAGA** Expert Advisory Group on AIDS

**PHLS** Public Health Laboratory Service



## How to reduce the risk?

From the end of 1982 it was apparent that measures were needed to reduce the risk which AIDS presented to the blood supply.

Until it was clear that the cause of AIDS was a virus transmitted by blood and it was possible to identify the virus itself, it would not have been possible with any confidence to eliminate the risks altogether. The risks could at best be reduced. Of the number of ways already described for reducing the risk from blood transfusions,<sup>562</sup> one was screening blood and plasma indirectly, by reference to the presence of some other marker in the blood.<sup>563</sup>

The most effective risk reduction measure which was suggested until the development of a better screening test was a donor leaflet and questionnaire, relying on donors' altruism and honesty with regard to their exposure to risk. This is addressed elsewhere in this Report.<sup>564</sup>

## Once the virus was known in the US

More effective screening began after Professor Robert Gallo announced his "discovery"<sup>565</sup> of the virus which led to AIDS. He did so at a press conference on 23 April 1984. He termed it "HTLV-III".<sup>566</sup> At this conference, there was international focus on using this discovery to develop a test specific for the virus. The US Secretary of State for the Department of Health and Human Services ("DHHS"), who was present at the press conference, predicted there would be a test to screen blood widely available within six months.<sup>567</sup> Five pharmaceutical companies in the US were chosen in early June 1984 to manufacture blood tests<sup>568</sup> and the US sought to establish world leadership.

Work however also proceeded in the UK. Dr (later Professor) Richard Tedder<sup>569</sup> and Professor Robin Weiss<sup>570</sup> began to develop a viable test. By the end of June, they said that

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562 See the chapter on *Response to Risk by the Blood Services*.

563 See the chapter on *HIV Surrogate Screening*.

564 See the chapter on *Role of Government: Response to Risk*.

565 There has been a degree of controversy about his claim to have discovered it. It was the same viral entity that Professor Luc Montagnier had identified as LAV (lymphadenopathy associated virus) a year earlier: eventually, after a number of years, the controversy was resolved with the award of the Nobel Prize to Professors Montagnier and Françoise Barré-Sinoussi. It is not an issue, however, which this Inquiry needs to address.

566 He had been working on a thesis that the HTLV virus was likely to be responsible for AIDS, and this label suggested that the virus now known as HIV was related to the HTLV viruses. Evidence before the Inquiry suggests that the link is tenuous: Written Statement of Professor Richard Tedder paras 42-47 WITN3436003. In the text which follows the label has been presented as HTLV-3, rather than adopt Roman numerals, except where there is a quote from a document in which HTLV III is used.

567 Background on AIDS Virus 23 April 1984 DHSC0000455, Letter from Dr J McGinnis to colleagues 9 May 1984 p3 DHSC0000583

568 Culliton *Crash Development of AIDS Test Nears Goal* Science 14 September 1984 pp1-2 DHSC0002247\_005

569 Middlesex Hospital.

570 Chester Beatty Institute. Professor Weiss had already written an article in *Nature* on 3 May 1984 to say that "*There no longer seems to be any doubt that AIDS is caused by an infectious agent*", noting that the "overload" theory could not explain why a single transfusion could lead to AIDS, nor explain vertical transmission from an affected mother to her infant. He emphasised that enzyme-linked

a test should be available within the foreseeable future.<sup>571</sup> The National Blood Transfusion Service (“BTS”) agreed at a meeting with Dr Tedder that it would start appraisal of their test as soon as possible.<sup>572</sup> By 3 July 1984, Dr Harold Gunson (consultant adviser to the Chief Medical Officer on blood transfusion) had reported to Dr Alison Smithies at the Department of Health and Social Security (“DHSS”) on this meeting, anticipating that a major decision to proceed to routine screening of all blood would be required. He added: *“it would be an advantage for the NBTS if this was in the format of the BPL RIA [Blood Products Laboratory radioimmunoassay] test for HBsAg and this concept is being considered by Richard Tedder at present.”*<sup>573</sup>

That a test was important, and needed soon was not lost on the DHSS: an internal minute was written on 10 July expressing the view that it was of *“paramount”* importance to ensure that public confidence in the National Blood Transfusion Service was maintained: *“And surely with all the concern over AIDS this can only be done ... by introducing a screening test as quickly as possible. We simply must ensure that ‘our’ blood is OK by the most up to date means.”*<sup>574</sup> The minute proposed that the DHSS should take *“a very strong line”*, which would involve pressing those concerned to get on with research and development as quickly as possible, marketing via CAMR<sup>575</sup>/Industry to be lined up *“as soon as may be”*, giving whatever help was needed to *“move this along”* (including going to ministers for money if needed), and considering the financial and other implications for the NBTS of mounting a screening service (*“again we may need to go to Ministers for special treatment”*). The minute ended: *“In short we must give this top priority.”*

By 11 July, the timescale before a test would be available became clearer. It was then said to be likely to be ready within the next eight weeks or so for trial at the North London Blood Transfusion Centre (Edgware) and then at Bristol and Manchester.<sup>576</sup> The implications of instituting a testing regime suggested there was an urgent need for a working party on AIDS

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immunosorbent assay (“ELISA”) screening tests for blood supplies were *“urgently needed”*: note the word “urgently”. Weiss *Retroviruses linked with AIDS* Nature 3 May 1984 BAYP0000026\_107

571 Letter from Dr Gunson to Dr Smithies 3 July 1984 p1 PRSE0003901

572 Letter from Dr Gunson to Dr Smithies 3 July 1984 p1 PRSE0003901. Various UK tests were available, probably, from mid July 1984. Professor Richard Tedder Transcript 13 October 2022 p107 INQY1000255. However, though these were in use in laboratories, there was little widespread knowledge of this at the time.

573 Letter from Dr Gunson to Dr Smithies 3 July 1984 p2 PRSE0003901. “RIA” stands for radioimmunoassay; “HBsAg” is the notation for the surface antigen in Hepatitis B infections. The RIA test for HBsAg was the one used to screen out Hepatitis B from all blood donations, and thus it was a type of test with which regional transfusion centres (“RTCs”) were fully familiar and for which they had the necessary equipment. Dr Gunson did however observe that *“To carry out such routine screening I should think that every R.T.C. will require additional staff and equipment, and some will require additional space.”* He was also conscious of the need to provide for scaling up production of the antigen.

574 Memo from Dr Michael Abrams to Dr Smithies 10 July 1984 DHSC0001574

575 Porton Down: CAMR stands for the Centre for Applied Microbiology and Research.

576 At a meeting of regional transfusion directors at the Communicable Disease Surveillance Centre in Colindale. Dr Spence Galbraith, Dr Tedder, and Dr John Craske were all present. Letter from Dr Ian Fraser to Dr Smithies 16 July 1984 DHSC0000448

“as when the screening test for this disease is generally available there will be numerous problems to sort out.”<sup>577</sup>

Just over two weeks later there was an important internal minute within the DHSS from Dr Smithies to Dr Michael Abrams.<sup>578</sup> It echoed the call made by the regional transfusion directors for a working party (the minute suggested an invited “group of experts”) to plan ahead to give guidance to health authorities as to how the “many problems that will need solving as a consequence of being able to detecte [sic] the antibody in carriers” might be resolved. It showed how fast progress was being made towards the development of a radioimmunoassay (“RIA”) test for HIV. Some 2,000 tests had already been carried out on AIDS patients, patients with the extended lymphadenopathy syndrome, homosexual patients attending sexually transmitted disease clinics, people with haemophilia and others. The findings were concerning.<sup>579</sup> The memo said that it was planned to start screening all blood donors at North London Regional Transfusion Centre in October.

The minute attached a paper. It spoke of the urgent need to seek advice; highlighted that fewer than 20% of patients had survived more than two years after AIDS had been diagnosed; that the number suffering in the US (and by implication, therefore, the UK), was expected to double within six months; and that: “*The importance of a screening test for the UK National Blood Transfusion Service is paramount. Whilst the risk calculated so far of AIDS being transmitted through ordinary blood transfusions is minimal, recipients of blood derivatives such as Factor VIII which are mainly extracted from large plasma pools are at greatly increased risk of having the disease transmitted.*”<sup>580</sup> It anticipated the need to scale up reagent production sufficiently to extend the screening test to two more centres beyond the North London Blood Transfusion Centre, and that if in preliminary trials the UK test was found to be accurate there would be a need to scale up production of the reagent further, for which CAMR<sup>581</sup> would be appropriate since it had the equipment and the expertise.<sup>582</sup>

577 Letter from Dr Ian Fraser to Dr Smithies 16 July 1984 p2 DHSC0000448. Such a group had actually been proposed on a UK-wide basis by the Scottish National Blood Transfusion Service (“SNBTS”) directors five months earlier, who said that such a group should be encouraged to mount donor screening studies. Minutes of SNBTS meeting 7 February 1984 p4 SBTS0000615\_042. Dr John Cash, SNBTS medical director, duly wrote on 15 February to the Scottish Home and Health Department to convey this conclusion. Letter from Dr Cash to Dr Albert Bell 15 February 1984 PRSE0003911

578 Note from Dr Smithies to Dr Abrams 27 July 1984 DHSC0000628. Dr Abrams was the Deputy Chief Medical Officer in England from 1985 to 1992.

579 “*The findings shortly to be published, confirm the presence of detectable antibody in 28 out of 29 (96 per cent) AIDS patients 104 out of 117 (88 per cent) patients with extended lymphadenopathy syndrome 60 out of 288, homosexual patients attending STD clinics (20 per cent) who were apparently otherwise healthy barring their ‘normal sexually transmitted disease’.*” Note from Dr Smithies to Dr Abrams 27 July 1984 p1 DHSC0000628

580 Aids Immune Deficiency Syndrome [AIDS] – Current Developments p2 DHSC0003615\_010

581 It was also anticipated that the test being developed by Professor Weiss and Dr Tedder was likely to cost less than 5% of the cost of US pharmaceutical products (20p as against “up to £5” per test). Aids Immune Deficiency Syndrome [AIDS] – Current Developments p3 DHSC0003615\_010

582 Within four days, the minute led to an internal meeting on 31 July at the DHSS. It was agreed ministers should be made aware of the screening of all donors at the North West London RTC proposed to start in October, and “*the need to find funding to scale up production of the test reagent*”. The meeting discussed further the “*need*” to set up a working group and its terms of reference, and tried to look for a way which would enable the Government “*to take credit*” for supporting development of the test. Memo from R Cunningham to Dr Smithies 31 July 1984 DHSC0000445

Things happened even faster than predicted. By the end of August, *The Guardian* announced that indeed a test had been developed;<sup>583</sup> the use of it was reported in *The Lancet* the following day,<sup>584</sup> and the DHSS in a briefing note concluded that the Tedder/Weiss test “*appears to be sensitive and specific and is possibly more reliable than other tests currently available in the USA and elsewhere.*”<sup>585</sup> The report in *The Lancet* had chilling implications: 34% of people with haemophilia receiving pooled clotting factors had tested positive.<sup>586</sup>

## Was there delay after this?

Thus, in the four months since Professor Gallo held his press conference, tests had been developed which were capable of identifying the HIV virus (then known as HTLV-3), both in the US<sup>587</sup> and the UK. The need for a screening test had been described as “*paramount*” in a paper produced within the DHSS. There was a need to resolve the problems and questions that would arise once there was a screening test. But repeatedly the need for this to be done quickly had been emphasised.

Yet, although within a matter of months tests became available, and in use, from a variety of manufacturers,<sup>588</sup> it was not until over a year later that blood donations throughout the UK were regularly screened in order to exclude HIV from entering the blood supply. Within that period a number of transfusions transmitted the virus to recipients, and plasma pools created to produce factor concentrates for the treatment of haemophilia were also infected. It is difficult to know precisely how many infections resulted, and how many deaths might have been avoided if screening had taken place earlier. The probability is that some could have been.

Though the passage of some time was to be expected,<sup>589</sup> the reasons for taking this amount of time require careful scrutiny.

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583 The Guardian *Study confirms fears on spread of Aids* 31 August 1984 PRSE0004233

584 Cheingsong-Popov et al *Prevalence of Antibody to Human T-Lymphotropic Virus Type III in AIDS and AIDS-Risk Patients in Britain* *The Lancet* 1 September 1984 NHBT0000068\_015

585 Memo from M Arthur to Mr Cashman and C Joyce 31 Aug 1984 p2 DHSC0000443

586 Cheingsong-Popov et al *Prevalence of Antibody to Human T-Lymphotropic Virus Type III in AIDS and AIDS-Risk Patients in Britain* *The Lancet* 1 September 1984 p3 NHBT0000068\_015

587 This is clear from the wording quoted just above in the text, where it speaks of “*other tests currently available in the USA*”. Availability is likely to have been for diagnostic purposes rather than for screening more generally: there is no material available to the Inquiry which suggests that any had yet been produced at scale.

588 The Gallo cell line and technical assistance were provided to selected US pharmaceutical companies soon after the press conference on 23 April 1984. Budiansky *Test companies chosen* *Nature* 5 July 1984 DHSC0001575. This “head start” led to tests being trialled, and then three US tests being licensed on 2 March 1985. The market leader was that produced by Abbott Laboratories Ltd: the American Red Cross signed an agreement immediately when it was licensed, and announced plans to begin phasing in the assay within days. National implementation was expected within two to six weeks. AIDS Center News *Clinical Management Update No. 2: Approach to the Clinical Management of Hemophilia Patients at Risk for AIDS or the AIDS-Related Complex* April 1985 p5 BART0000795. Very quickly, a number of European countries and Australia began to announce the start of universal screening of blood donations: Presentation on the International Understanding of, and Response to, Risk of Hepatitis and HIV/AIDs January 2023 INQY0000439

589 Essentially to scale up the tests for mass screening.



Well before the start of the period of just over 13 months from August 1984, when a test was used but not yet widely available, until October 1985 when it came into universal use, the public had been alerted by the media to the risk that the AIDS epidemic might spread from the US to the UK. Politicians were alert to this too. By August 1984 they were alert to the possibilities of testing to protect people who needed transfusion. In mid November Lord Simon Glenarthur, the Parliamentary Under-Secretary for Health in the Lords, queried whether all blood was now being screened for AIDS and if not said he would like to know when the UK would be able to do this, and whether there were any problems associated with this if the technology existed.<sup>590</sup> It was an understandable enquiry, though with the UK no longer on the edge of, but by now some way into, a public health crisis<sup>591</sup> it is surprising that he needed to ask his civil servants these questions rather than having been well briefed by them already.<sup>592</sup>

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590 Note from S Ghagan to Alun Williams 15 November 1984 p2 DHSC0002309\_055. The fact there were likely to be practical problems (what to tell those who tested positive; whether people in the gay community or those who had injected drugs might donate in order to be tested; whether to introduce the test piecemeal across the country or all at once; if it was to be introduced piecemeal, should any area or group be targeted for first receipt or pilot schemes; whether regional or central funds were to finance any additional equipment; how to maintain sufficient supplies; and whether “first-generation” tests might be adopted if it were known that a more sensitive or specific second-generation test was on the way) had been highlighted as early as February, the need for a working party to report on how best to deal with them had been called for then, and emphasised as “urgent” by regional transfusion directors in July – but it seems that the Minister had not been kept abreast of developments. This was not his fault, but calls into question the judgements as to what to put across his desk for his information, attention, and action.

591 This is borne out by considering snapshots of what had appeared in the media. In addition to articles in various papers in May 1983, as recorded in the chapter on the *Knowledge of the Risks of AIDS*, by the end of the year *The Guardian*, in what may be seen as measured tones, had argued that: “*Our own Government’s response to what may prove a major medical and social problem here has so far been slow and insufficient ... Mr Norman Fowler may soon have to explain convincingly why he has maintained his decision to depend largely on American Factor VIII blood for Britain’s haemophiliacs, instead of continuing to buy from countries where Aids is not prevalent, or seeking to become self-sufficient.*” *The Guardian Panic and the blood* 2 November 1983 DHSC0003824\_107. It was in October 1983 that Dr (later Sir) Donald Acheson became Chief Medical Officer (“CMO”). He says in his autobiography that: “*As far as HIV/Aids was concerned, a few cases of what was already seen as a fatal virus infection associated with infected blood and sexual intercourse had already occurred prior to my appointment. I decided that the implications of the infection was [sic] so serious and our knowledge so limited that I should seek expert advice as soon as possible.*” Emphasis added. Acheson *One Doctor’s Odyssey: The Social Lesion* 2007 p15 WITN0771088. Matters escalated over the following year before Lord Glenarthur’s query, as illustrated by the opening to an obituary for Sir Donald Acheson: “*His term coincided with the advent of Aids and an outbreak of BSE [bovine spongiform encephalopathy], the former having particular potential for public alarm. When Acheson took over, the country had seen fewer than 30 cases; within two years 121 people had died, and a further 10,000 were thought to have the condition.*” *The Telegraph Obituary of Sir Donald Acheson* 20 September 2023 p1 RLIT0002199

592 Lord Glenarthur had been given a briefing note on 31 August: Memo from M Arthur to Mr Cashman and C Joyce 31 Aug 1984 DHSC0000443, referred to above. However, he was told it would be some time before the results of trials could be evaluated, but he had had no further briefing: hence his query which was responded to on 26 November 1984. Memo from Alun Williams to Mr Joyce 26 November 1984 p1 DHSC0002309\_055. Written Statement of Lord Simon Glenarthur para 49.1, para 54.1 WITN5282001. A more general note (which was copied to Lord Glenarthur’s private office) on the “*current situation on AIDS*” was also provided on 19 November 1984 in response to a request from the Secretary of State. Note from Dr Smithies to Mr Godber 19 November 1984 DHSC0002309\_053. In a public health crisis, it might be thought that ministers should receive regular updates, even if it is simply to say that no progress has been made.



The first cautionary note then arose: Kenneth Clarke<sup>593</sup> as Minister of State for Health is recorded as having strong views that spending the £2 million which would be necessary for screening would not be cost effective “*when there were so few AIDS cases*” and that “*the money could be better spent elsewhere*.”<sup>594</sup> He decided that use of the central reserve fund would be inappropriate,<sup>595</sup> and the cost should be met from the existing budgets of regional health authorities. Lord Glenarthur was briefed that there were “*numerous medical and ethical implications of such testing*” which were due to be examined by a working group on AIDS.<sup>596</sup> This was already November 1984: a working group had only been newly formed.

At the working group’s first meeting on 27 November 1984 – thus some nine months after Dr (later Professor) John Cash had suggested that there should be a UK-wide<sup>597</sup> working group – it continued to express enthusiasm and urgency concerning testing: it came to a “*unanimous strong view*” that antibody tests for HTLV-3 “*must be used for all NBTS donors as soon as possible*.”<sup>598</sup> Though regional transfusion directors subsequently described the meeting as “*unproductive*” (there was “*no new leaflet, no finance and no positive move towards full donor screening*”)<sup>599</sup> there was at least an agreement “*to test all donors once an antibody test was available*.”<sup>600</sup> Dr Cash was yet more scathing. He wrote to Dr Albert Bell of the Scottish Home and Health Department (“SHHD”) (just two months later) to say that Dr Richard Lane (director of the Blood Products Laboratory (“BPL”)) and Dr Gunson “*described the fiasco which emerged at DHSS on the 27th November*” in respect of HIV screening.<sup>601</sup>

Dr Brian McClelland’s written report of the meeting has his overview of screening tests underlined in it: “*I can get no clear picture of when or how a serviceable assay will be*

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593 Later Lord Clarke.

594 Memo from Dr Abrams to Dr Smithies 23 Nov 1984 DHSC0000435. He confirmed this as an accurate reflection of his view at the time, though recognised that with hindsight it was “*a tragically – an incorrect opinion*” but explained “*that was when we got just a handful of AIDS cases*.” Lord Kenneth Clarke Transcript 28 July 2021 p59 INQY1000142

595 Note from S Ghagan to Alun Williams 15 November 1984 p1 DHSC0002309\_055

596 Note from S Ghagan to Alun Williams 15 November 1984 p1 DHSC0002309\_055

597 There still was not: the Scottish presence was as observers. Letter from Dr Cash to Dr Albert Bell 24 January 1985 p1 PRSE0004386, Letter from Dr Cash to Dr Albert Bell 15 February 1984 PRSE0003911

598 Emphasis added. Memo from Dr Abrams to Dr Edmund Harris 27 November 1984 p1 DHSC0002251\_011. This is a note of the meeting prepared by Dr Abrams for the DCMO Dr Edmund Harris. It has a different view of the meeting – that “*it went off reasonable [sic] well*” – from the other recorded views. Compare, for instance, Dr McClelland’s note of the same meeting at: Report on Meeting of Advisory Group on AIDS 27 November 1984 PRSE0004191. No formal minutes of the meeting have been located.

599 Minutes of Regional Transfusion Directors meeting 23 January 1985 p1 PRSE0002062

600 Minutes of SNBTS Directors meeting 11 December 1984 p3 PRSE0001767

601 Letter from Dr Cash to Dr Bell 24 January 1985 p2 PRSE0004386. He complained there were still “*just no mechanisms in the UK for these crucially important topics [“Screening Blood and Plasma” and “Recommendations for the Individual”] to be discussed, openly and confidentially, and for clear, co-ordinated policies to emerge*”, and of “*a fragmented organisation led by the Department of Health which, as far as I can see, in terms of this aspect of the NHS, is lost and floundering in an increasingly high profile*.” Letter from Dr Cash to Dr Bell 24 January 1985 pp2-3 PRSE0004386

*provided*.<sup>602</sup> The report of the meeting to the Deputy Chief Medical Officer (“DCMO”) described this in less stark terms, but to the same effect: “[Those participating in the meeting] *hoped that the Tedder/Weiss test could be scaled up very quickly – Professor Weiss pointed out some of the problems of doing this.*” The report did not elaborate on the problems he foresaw, but the words which follow are: “*If test kits are limited initially they should be used first in*”<sup>603</sup> which suggests that it was seen as a real possibility that scaling up would be a drawn out process. It is clear that problems in producing a test kit for use both universally and speedily across the UK were foreseen. There is no record of a strategy to overcome them.

Dr McClelland’s record confirms that one problem was the need to find a way to produce enough test kits rapidly enough, since it records that “*Weiss/Tedder/DHSS appear to be negotiating*” with Wellcome,<sup>604</sup> and with other less interested commercial producers – a clear recognition that neither Professor Weiss’s nor Dr Tedder’s laboratories could on their own, or together, produce enough to do more than was currently being made – enough to test samples referred to them, but little more. A commercial producer was plainly going to be needed, unless BPL were to step in: and the report shows that though Dr Lane was keen to offer their services, the meeting understood that the DHSS had little enthusiasm for his bid.<sup>605</sup>

Under pressure from media reports in late December that one donor who subsequently developed AIDS had given blood which had apparently transmitted the virus to three people – a mother, her baby and a 78-year-old man – (about which ministers had been made aware 20 days beforehand)<sup>606</sup> the Chief Medical Officer (“CMO”) made a public statement on 20 December,<sup>607</sup> and in the same press release the DHSS said that testing was being developed: but there was still “*considerable work needed to ensure that any such test is reliable and suitable for routine use.*”<sup>608</sup>

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602 Report on Advisory Group on AIDS meeting 27 November 1984 p2 PRSE0004191, Dr Brian McClelland Transcript 28 January 2022 p36 INQY1000178

603 Memo from Dr Abrams to Dr Harris 27 November 1984 p1 DHSC0002251\_011

604 Then a pharmaceutical company. In 1995 Wellcome Plc was bought by Glaxo to form GlaxoWellcome, which later became GlaxoSmithKline. Today, the Wellcome Trust is a charity funding health research.

605 This was plainly correct. The bid was unrealistic, especially given the limited state of any research and production facilities then available at BPL which still was two years away from the completion of the rebuilding project which was then ongoing, and which was struggling to cope with demands for the production of enough NHS factor concentrate in any event. BPL also had no experience in propagating retroviruses according to Professor Weiss. Written Statement of Professor Robert Weiss para 5.68 WITN6868001

606 Ministers were briefed that three recipients had become seropositive, and that there was likely to be press interest. *The Guardian* then reported that one of the recipients was a mother whose baby was then infected: *The Guardian Blood donor passes Aids virus to baby / Brighton* 20 December 1984 NHBT0000024\_005. The briefing also explained that the donor’s plasma had been used for Factor 8 and given to 38 people with haemophilia who were therefore at risk and being followed up. In addition, two other donors had been found to be seropositive and the recipients of their seventeen donations over the previous five years were being followed up. Memo from Alun Williams to Mr Joyce 30 November 1984 DHSC0002309\_057

607 He identified a mother, a 78-year-old man, and a third, a man of about 40 years old. Memo from Alun Williams to all Regional Transfusion Directors 21 December 1984 p2 BART0000814

608 The press statement by the DHSS seems to have assumed that the Minister of State for Health would accept the Department’s view that screening of blood donations was essential. Memo from Alun Williams to all Regional Transfusion Directors 21 December 1984 p3 BART0000814, Memo from Alun Williams to Mr Joyce 30 November 1984 DHSC0002309\_057

Dr Smithies sent a position paper on AIDS to the CMO on New Year's Eve. She described how Professor Weiss and Dr Tedder had negotiated with Wellcome to develop their UK test, and that Wellcome had in turn sub-contracted CAMR Porton where an infective material like the virus could be contained and sufficient enough of it replicated to enable effective testing for its presence in human blood. However, at that stage she said she understood that *"the Wellcome/CAMR initial effort will be directed to produce antigen which could be used by the Blood Products Laboratory (BPL) to make the screening test"*. The British test was likely to be cheaper, more sensitive and more specific than US products. She wrote: *"It is not possible to predict when this test will be available for universal use in the RTCs because a number of scientific problems have to be overcome, but with luck it may be available although less well validated at about the time that the test from the USA will be on the market, that is in the first quarter of 1985."*<sup>609</sup>

Within a week an internal DHSS note further recorded general agreement that the Tedder/Weiss test was the *"most sensitive RIA for HTLV III presently available."*<sup>610</sup>

At this stage, the DHSS seems to have been set on an RIA test, which in practice favoured the UK offering. This is because the regional transfusion centres ("RTCs") in the UK regularly used an RIA test to screen blood for Hepatitis B, and so were both equipped to run such a test and familiar with it. The US test kits were all of the ELISA type,<sup>611</sup> which involved no radioactivity (as distinct from an RIA test) but which was the test of the future – cheaper, more reliable, easier to scale up for mass production, easier to use once operators were familiar with it – but which would require new equipment and some training if it were to be adopted across the UK. The evidence of Professor Tedder himself as to the position in January 1985 was that *"we were already thinking that we needed to get away from RIA to EIA"*.<sup>612</sup> He said that although the Middlesex Hospital where he worked, and the Chester Beatty Laboratory where Professor Weiss was based, were able to make a reproducible, stable, successful test they would not be able with their resources to produce one on the commercial scale needed for universal screening across the UK. A partner was needed, with the facilities and experience to do so. He considered that involving Wellcome in scaling up production of an RIA test (if that was to be the nature of the test) made little sense since

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609 Note from Dr Smithies to Dr Mary Sibellas containing a draft position paper on AIDS and its Prevention in the UK 31 December 1984 p3 DHSC0001693. "Sensitivity" refers to the extent to which a test will identify every viral particle (and not give false negatives, even if it also identifies a number of false positives); "specificity" is the extent to which it correctly identifies the absence of relevant viral particles (and does not give false positives). The closest to an assurance that everything which is the virus of interest is identified and eliminated, and everything which is not is identified so that it does not have to be eliminated, is a combination of sensitivity and specificity.

610 Further Development and Establishment for Routine Use in the Blood Transfusion Service of a Screening Test for AIDS 4 January 1985 p1 DHSC0002255\_039

611 Enzyme-linked immunosorbent assay.

612 Enzyme immunosorbent assay – in essence the same as ELISA, using enzymes rather than the radioactive isotopes in an RIA test. Professor Richard Tedder Transcript 14 October 2022 p13 INQY1000256. This was very much a retrospective recollection, and the feeling he described may have come a little later in 1985 since his view finds no echo in any contemporaneous document available to the Inquiry from January 1985, though it was ELISA tests that Professor Weiss had called for in *Nature* in May 1984: Weiss *Retroviruses linked with AIDS* *Nature* 3 May 1984 p2 BAYP0000026\_107

their expertise was in scaling up enzyme-linked tests. They had none in producing RIA tests at volume, and ELISA tests were gaining favour generally.

Professor Tedder's evidence was that he was not involved in any negotiation with Wellcome, such as had been referred to at the November meeting of the working group.<sup>613</sup> Professor Weiss for his part said he had been "*barely involved*": their institutions and the institutional business advisers did any negotiating. He could not say if, and if so how much, DHSS were involved in this.<sup>614</sup> He was however clear that Wellcome Diagnostics Ltd proposed to substitute ELISA for RIA in a screening test based on the competitive<sup>615</sup> HIV antibody test that Dr Tedder and he had developed as a research tool, and they had readily agreed.<sup>616</sup>

The case for favouring an RIA test must logically have disappeared once Wellcome had indicated that they would produce an ELISA test, with the agreement of Professor Weiss and Dr Tedder, since the only way that sufficient test kits could be provided for universal screening was with the involvement of a commercial producer familiar with the available technology. If they would not produce it in RIA format, it would be difficult to find anyone who would.<sup>617</sup>

Pressure from transfusion directors continued throughout January. Dr McClelland wrote on 8 January on behalf of the regional transfusion directors of Scotland to Wellcome to express concern about the apparent lack of progress, and say: "*I really cannot over emphasise the urgency of this situation*". He wished there to be "*no doubt of the extreme pressure being placed [from recent press coverage] on the transfusion services to ensure that no 'high risk donors' donate blood – a task which is essentially quite impossible unless some form of screening test is available.*"<sup>618</sup> It was plain that his standpoint was one of providing the greatest protection to the public as soon as possible, even if (so far as screening tests were concerned) later products might prove to be better than those available sooner: "*I would emphasise that in my own Centre at least, we would be very prepared to use, in the interim, some form of test procedure which might be considered less than satisfactory for a large scale, long term screening programme*" and that if even a limited supply of materials was available it would be "*a tremendous step forward*".<sup>619</sup> One of the features of what happened

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613 Professor Richard Tedder Transcript 14 October 2022 p3 INQY1000256

614 Written Statement of Professor Robert Weiss para 5.57 WITN6868001

615 This was the aspect of the test Professor Tedder was most keen to stress during his evidence: he was less concerned with whether the test used radioactivity or enzymes to produce readable signals than that it was a competitive test, and that it was a one-step test as opposed to a two-step one. Professor Richard Tedder Transcript 13 October 2022 pp86-88 INQY1000255

616 Written Statement of Professor Robert Weiss para 5.62 WITN6868001

617 Except BPL, who for good reason had been discounted as serious contenders for the task. See: Minutes of Regional Transfusion Directors meeting 23 January 1985 p1 PRSE0002062

618 Letter from Dr McClelland to C Madden 8 January 1985 p2 PRSE0000750. In his evidence Dr McClelland explained that he approached Wellcome because they were the only UK-based manufacturer and he was not optimistic about getting a positive response from US suppliers. Dr Brian McClelland Transcript 28 January 2022 pp65-68 INQY1000178

619 The letter began with the words: "*I am writing to you on behalf of the Regional Transfusion Directors in Scotland to ask if you are in a position to give any encouragement about the likely availability of some form of HTLVIII antibody test in the near future. This has been a matter of great concern to us, as to all transfusion people, since the significance of positive antibody testing began to emerge almost a year ago.*" His view as stated in his written statement was that some improvement in safety could be achieved for at least some patients (eg the very young or pregnant mothers) by using a test that had



throughout the history of the introduction of screening for HIV and Hepatitis C is that the approach of Dr McClelland illustrated here and of those who took the same view – that “some protection, despite its shortcomings, is better than none” – was generally rejected in favour of the view that can be summarised as “no test with shortcomings should be introduced: let us wait until we can identify the one with least”.

Matters culminated in early January 1985. There was a submission to ministers seeking approval in principle for a screening test for AIDS antibodies in the NBTS, referring to the Tedder/Weiss test which was by then being used at both the Middlesex Hospital and the Central Public Health Laboratory at Colindale.<sup>620</sup>

The approval in principle sought by the submission was granted.<sup>621</sup>

On 16 January Professor Bloom wrote to the DHSS, arguing for the provision of central funding for more staff for Professor Weiss and Dr Tedder, and to ensure that there should be adequate funding to develop British HTLV-3 antibody test kits, work which was “*of utmost importance*” to meet what he described as an “*emergency situation*.”<sup>622</sup>

Until 16 January there had been some expression of urgency in the Department of Health’s approach, at least since the late autumn of 1984. There was then something of a change of tune. On or just before 16 January, there was a telephone call between Dr Smithies and R Allen (Scientific and Technical branch). It related to setting up an evaluation programme on screening systems for AIDS markers.<sup>623</sup> R Allen drafted a letter for those pharmaceutical companies which might wish to market tests in the UK. They would all be written to, saying that the DHSS proposed to set up an evaluation programme for investigating the performance of screening test systems, the results of which would be used to give advice as to which ones RTC directors might wish to use. The heavy hint was that future sales of test kits were likely to depend on the results of this evaluation programme, for although regions had autonomy in purchasing, the DHSS anticipated “*issuing firm advice ... on which materials may be used by them in routine service*”, and the national blood transfusion services were to be advised which products to use, and the use of products which had not been tested would be discouraged.<sup>624</sup>

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not yet been through the full process of development and evaluation leading up to routine large-scale production, but that had been shown to be effective in detecting HIV antibody. Written Statement of Dr Brian McClelland para 398 WITN6666001

620 Memo from Dr Smithies to Dr Alderslade 11 January 1985 DHSC0000562

621 Memo from Kenneth Clarke MP to CMO 22 January 1985 DHSC0002482\_012. Kenneth Clarke MP wrote: “*This looks inevitable, I suppose ... How did Wellcome corner this market and why did they bring CAMR in? ... Also, as only haemophiliacs have died and they may have had Factor VIII from American blood, is it the case that we have not had one AIDS fatality from blood donated in this country yet? Do we need this and heat treatment of the blood?*”. Original emphasis. In evidence, he explained that the reference to “*only haemophiliacs*” was not intended to be belittling, but to convey that the only deaths from blood or blood products so far had been in people with haemophilia, and that this was because they had been given US blood products. Lord Kenneth Clarke Transcript 28 July 2021 pp69-73 INQY1000142

622 Letter from Professor Bloom to Dr Smithies 16 January 1985 OXUH0000412\_002

623 Memo from R Allen to Dr Smithies 16 January 1985 p1 DHSC0002257\_012

624 Memo from R Allen to Dr Smithies 16 January 1985 pp2-3 DHSC0002257\_012. The letter was issued as drafted with an additional enquiry about any approaches to units in the UK about carrying out trials.



It was at this stage that there was a delay which remains unexplained.

On 29 January, there was the first meeting of the Expert Advisory Group on AIDS (“EAGA”). Professor Weiss explained that work was currently being carried out with Wellcome Diagnostics Ltd to develop a screening test, but there were still problems to be solved and he was not able to say when the test would become available.<sup>625</sup> Yet the DHSS remained wedded to the idea of an RIA test, supported by the views of Dr Gunson.<sup>626</sup>

It took four weeks after receiving Professor Bloom’s letter emphasising the urgency of introducing a test for Dr Smithies to reply. She said that the Department was “*taking all practical steps*”. Those “*practical steps*” did not however involve actually utilising a test provided for evaluation. Nor did they involve reporting on the results of pilot studies as part of the evaluation – a pilot study had not yet begun, it appears. The evaluation had not yet started. Matters were still at the preliminary stage of “*arranging that all tests for antibody to HTLV III should be evaluated in order that recommendation can be made of the most suitable to use in the blood transfusion services and also by the NHS.*”<sup>627</sup>

The problem was not that commercial tests were not available for evaluation. Regional transfusion directors in Scotland had contemplated at the end of January pursuing their own evaluation unilaterally,<sup>628</sup> with a view to introducing a US test in the absence of progress toward a UK choice until the Scottish Home and Health Department put a stop to that because they had given assurances to the DHSS that Scotland would follow its lead.<sup>629</sup>

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Letter from R Allen to Jacques Ponteyne 22 January 1985 SHPL0000226\_099

- 625 Minutes from Expert Advisory Group on AIDS meeting p4 PRSE0002734. Professor Arie Zuckerman is then recorded referring to other products which were soon to be readily available, saying that tests were also being carried out at his laboratory and that the results of the US Dupont and Travenol tests might be available within a few months. Comparisons would be made with the test being developed by Professor Weiss and Dr Tedder. So far as introducing a test as a matter of urgency in the UK, the update from Professor Weiss might be expected to have given the DHSS further cause for concern about likely timescale. “*Spring*” for its introduction, as put in the submission to the Minister, was looking even more ambitious. Memo from Dr Smithies to Dr Alderslade 11 January 1985 p1 DHSC0000562
- 626 He told the first meeting of EAGA that “*there was an overwhelming preference for the use of the radioimmunoassay test in the NBTS.*” At a subsequent Central Blood Laboratories Authority meeting, he said that “*if the United Kingdom needed to be converted for enzyme testing it would pose a serious problem for the continuance of RIA testing. It was therefore considered vital that a British test be developed*” (ie an RIA test). Minutes of Central Blood Laboratories Authority meeting 1 February 1985 p6 DHSC0002325\_040
- 627 Letter from Dr Smithies to Professor Bloom 12 February 1985 HCDO0000003\_093. Emphasis added. This sluggish pace on the part of the DHSS is to be contrasted with the speed of the early response in the US, as described in: Culliton *Crash Development of AIDS Test Nears Goal* Science 14 September 1984 pp1-2 DHSC0002247\_005. Evaluation itself was a sensible approach, despite the fact that it would take some time to achieve, and the need for it was underlined by a report on the results of the Food and Drug Administration (“FDA”) evaluation of HTLV-3 antibody screening tests produced on 13 February 1985. US DHHS Statement on Results of FDA Evaluation of HTLV-III Antibody Screening Tests February 1985 DHSC0000608. This showed that a large number of false positive tests were liable to be produced, and underlined a need for there to be a comparative evaluation of the tests.
- 628 Letter from Dr Cash to Dr Bell 24 January 1985 p2 PRSE0004386, Letter from Dr Cash to Dr Ruthven Mitchell 25 January 1985 PRSE0001075
- 629 This is what Dr Cash told the Penrose Inquiry. Written Statement of John Cash for the Penrose Inquiry 8 September 2011 pp2-4 PRSE0003395

Over three weeks later, almost two months since Professor Bloom wrote expressing urgency, the DHSS was still saying that they had: “*firm plans to evaluate all the anti-HTLVIII kits that are marketed in the UK and this work will be started as soon as possible. An evaluation protocol is being devised and when it is ready all companies in the field will be given the opportunity to comment on it.*”<sup>630</sup>

Just ten days later, with yet no meaningful development in devising a protocol, Dr Smithies wrote to the chair of the regional transfusion directors in England to say (in part of her letter): “*I am sure you will agree that it is in the interest of the NBTS as a whole to delay the introduction of any routine screening tests until they have been properly evaluated and then to ensure that co-ordinated arrangements are made to use them at all centres.*”<sup>631</sup>

A number of questions had by now arisen. It was clear that the Wellcome test was not imminent; there had been a lack of understanding about whether the test would be of RIA or ELISA type; and the results of the Food and Drug Administration (“FDA”) evaluation confirmed the desirability of some evaluation in the UK. But there was, overall, a need for speed in the interests of patients’ safety and public health. The CMO began to confront these questions. He went one Friday evening late in March to Middlesex Hospital to meet Dr Tedder, Professor Weiss and Professor Michael Adler. They confirmed that though their test worked reasonably well as a laboratory tool, adequate scaling up was still to be achieved if it was to be used. It was agreed that it would probably be necessary for the NBTS to go ahead and use the first successful test that became available, which was unlikely to be the Tedder/Weiss competitive assay in the first place.<sup>632</sup> Armed with this information, the CMO told the DCMO that “*unresolved technical challenges facing the UK test mean that it is unlikely to be first in the field*” adding “*We are likely to need to evaluate a number of other tests, largely from the United States, over the succeeding months.*” He wanted to know who within the DHSS and Public Health Laboratory Service (“PHLS”) would be responsible and accountable for “*the completion of what will be a demanding series of evaluative tests.*”<sup>633</sup>

A month later, it appears to have been decided that the evaluation (which had still not begun) should take place in two stages: an initial laboratory stage, followed by a field test of those still considered suitable.<sup>634</sup> But an internal minute pointed out to the Parliamentary

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630 Letter from D Kennedy to Sarah Sparrow 5 March 1985 NHBT0000186\_024. Emphasis added. Delay is built into the rhetoric.

631 Letter from Dr Smithies to Dr Ian Fraser 15 March 1985 DHSC0000557. Emphasis added. As it happens, this plea to wait, and not to take precipitate unilateral action, did not dissuade Newcastle Public Health Laboratory Service from “going it alone” by using a test, apparently derived from Gallo’s cell line. Letter from Dr Harris to Dr J Whitehead 19 March 1985 DHSC0002263\_027

632 Minutes of meeting between CMO and Dr Tedder, Professor Weiss and Professor Adler 22 March 1985. Professor Tedder told the Inquiry that the way in which CAMR (Porton Down) had approached producing reagent for the test was disappointing: they had not done it in the manner they had been advised, and their method produced less antigen. Professor Richard Tedder Transcript 13 October 2022 p96 INQY1000255

633 Memo from Dr Acheson to Dr Abrams 25 March 1985 USOT0000016\_143

634 Expert Advisory Group on AIDS Screening Tests Sub Group Report on the Introduction of a Test for Antibody to the AIDS Related Virus 22 April 1985 p2 PRSE0002096, Minutes of Expert Advisory Group on AIDS meeting 22 April 1985 p3 PRSE0001239. Nothing is recorded about any discussion as to how quickly screening tests could be introduced.

Under-Secretary of State for Health (John Patten) that he had made an error when he told Parliament, in answer to a supplementary question on 16 April, that “*we hope to have a screening test within a few weeks*”: the minute said “*It would be more accurate to say that we hope to begin evaluating screening tests within the next few weeks.*”<sup>635</sup>

A month later still (now May), the evaluation had not yet begun. Dr Smithies however was asked by the CMO about progress towards screening in other countries. She was able to respond to him to say that in the US and Australia screening was already taking place; Finland had started it as routine; Switzerland was beginning; France expected to start by July; and West Germany had started testing as routine for the Red Cross and University Transfusions Services, and it was to be mandatory there no later than 1 October.<sup>636</sup>

On 29 May there was a meeting of EAGA. Progress was still being expressed in terms that anticipated a start, rather than reporting that there had been one. This time it was closer: the first two kits were to have their initial evaluation<sup>637</sup> in the next two weeks, and a third in the next four to six weeks. When the chairman<sup>638</sup> said that while it was important to introduce a reliable screening test as soon as possible “*an effective evaluation of the tests was essential and should not be rushed*”, Professor Bloom was the only person who is recorded as expressing concern about this delay.<sup>639</sup>

The day after this John Patten entered the fray. He questioned the CMO “*on the overall position and it is quite clear that Ministers need to know of the timescale for the evaluation of the test and, if satisfactory, for the introduction of the test at every transfusion centre.*” This prompted the DCMO to demand a critical path analysis from the PHLS director.<sup>640</sup>

In turn, the day after that, Professor Bloom wrote to the DCMO to reinforce the need for rapid introduction of a screening test. The prevalence of HIV was rising; not only people with haemophilia but other groups of patients “*could be at a real risk of infection by HTLV III. I therefore think that one or more of the FDA approved tests should be introduced immediately to test donations ... I feel that such testing should be implemented immediately in order to preserve confidence in the Blood Transfusion Service and any temporary increase in expense would just have to be borne.*” He gave notice that he planned, together with Dr Charles Rizza and Professor Charles Forbes, to write a letter to *The British Medical Journal* along those lines, concluding in the article that: “*Three commercial test kits have now been approved by the American Food and Drug Administration and, although there may*

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635 Memo from Alun Williams to M Harris and Ms McKessack April 1985 DHSC0000555. Emphasis added. The vagueness of “*the next few weeks*” expressed in mid April can be contrasted with the change to giving an actual number of weeks at EAGA on 29 May (see below). It seems the “*few weeks*” had not yet elapsed, but there would be (comparative) certainty by then.

636 Letter from Dr Smithies to Dr Abrams and Dr Hunt 20 May 1985 DHSC0002269\_054

637 At PHLS, Colindale.

638 Dr Harris.

639 Minutes of Expert Advisory Group on AIDS meeting 29 May 1985 pp2-3 DHSC6887719\_023

640 Letter from Dr Harris to M Harris 31 May 1985 DHSC0001503. Dated 31 May 1985, referring to the meeting the day before.

*be a small number of false positives, it is unreasonable to delay testing until this possibility is eliminated.*"<sup>641</sup>

A month later still, there was little to show significant progress: following a submission about the testing strategy,<sup>642</sup> Kenneth Clarke announced on 27 June that an "AIDS blood test would be introduced **within the next few months**."<sup>643</sup> He continued: "We believe that no test should be introduced in the UK until its reliability has been established. There is no point in introducing a test which often fails to detect antibodies in blood or detects antibodies where there are none ... We hope that we will be able to introduce a test within four to five months."<sup>644</sup> The press release recorded that the Government had provided funds to "enable" PHLs to carry out a full evaluation of all the test kits which were currently available.

In the nearly four months since the draft protocol was being "devised", itself some two months after the decision to evaluate all tests before recommending any for use, there had been developments elsewhere. On 2 March a test produced by Abbott Laboratories Ltd had been licensed for use by the FDA in the US;<sup>645</sup> in April the World Health Organization ("WHO") had concluded at a conference that countries should "Screen, where feasible, potential donors of blood and plasma for antibody to LAV/HTLV-III";<sup>646</sup> and by May 1985 most of the plasma centres in the US were testing donations for the presence of HIV antibodies, as well as US blood banks testing blood.<sup>647</sup> Other countries were ahead of the UK, just as the CMO had been told.

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641 Letter from Professor Bloom to Dr Harris 31 May 1985 DHSC0002489\_099. The article was published on 22 June. Bloom et al *Letter to the Editor on HTLV-III, haemophilia, and blood transfusion* British Medical Journal 22 June 1985 PRSE0001917. There was a reply, not until 8 July, from the DCMO: "It is accepted policy that the screening of blood donations should be introduced as soon as possible. However, it is clear from the evidence available that the performance of diagnostic kits licensed by the FDA is variable. It seems prudent therefore that before any large scale introduction of them into the Blood Transfusion Service they should be properly evaluated in the UK ... Whilst the introduction of an unevaluated test into the Blood Transfusion Service and simply discarding any blood which gives a positive reaction is superficially attractive we are not persuaded this is the right course." Letter from Dr Harris to Professor Bloom 8 July 1985 DHSC0001183

642 Paper titled: Screening of Blood Donations for AIDS 7 June 1985 DHSC0002311\_019, Letter from Dr Acheson to John Patten 10 June 1985 DHSC0002311\_021. The submission suggested that there would be merit in making the DHSS's approach public once it had been agreed because "This could take presentational advantage of the extra funding for PHLs as well as stressing the importance of safeguarding the BTS as soon as possible whilst not impairing its operational efficiency. Having such a statement on record could be helpful if a well publicised case of AIDS attributable to infected blood occurs."

643 Emphasis added. Department of Health and Social Security Press Release *AIDS Blood Test Soon to be Available* 27 June 1985 p1 DHSC0001184

644 This is looking, therefore, at the introduction of a test between early October and early November, for something which had been unanimously agreed by officials during the previous November to be urgently needed.

645 AIDS Center News *Clinical Management Update No. 2: Approach to the Clinical Management of Hemophilia Patients at Risk for AIDS or the AIDS-Related Complex* April 1985 p5 BART0000795. Abbott was the market leader. The FDA also licensed tests by Electro-Nucleonics and Litton-Bionetics and two further companies had applied for FDA authorisation.

646 15-17 April 1985 in Atlanta, US. World Health Organization *World Health Organization Workshop: Conclusions and Recommendations on Acquired Immunodeficiency Syndrome* Morbidity and Mortality Weekly Report 17 May 1985 p2 BPLL0004935\_079

647 Counsel Presentation on Pharmaceutical Companies: Response to Risk 1 November 2021 p80 INQY0000311



Though there was no restriction on the marketing of test kits in the UK by pharmaceutical companies, there was no approval of any one of them, and it is plain that none was encouraged. The policy of introducing a screening test “*as soon as possible*” was belied, so far as those last four words are concerned, by what happened.

It was finally three weeks after Kenneth Clarke’s statement – on 15 July 1985 – that there was a draft report from PHLS providing the raw data arising from the initial evaluation, for further discussion.<sup>648</sup>

On 30 July, the results were reported to EAGA. PHLS recommended three tests as most suitable for use in diagnostic laboratories: one produced by Organon Teknika Ltd; a second by Wellcome Diagnostics Ltd; and a third by Ortho Diagnostic Systems Ltd. (The “Organon”, “Wellcome” and “Ortho” tests). The Organon and Wellcome tests were regarded as particularly suitable for use in blood transfusion centres.<sup>649</sup>

The determination originally expressed that there should be full evaluation before recommending any one test for use was itself not followed through to its logical conclusion. The protocol had envisaged a two-stage process. The second stage was a field test. EAGA accepted advice from the regional transfusion directors that given “*the pressure to introduce routine screening in the BTS as soon as possible*”, screening should start in October before field tests had been completed as the protocol had envisaged.<sup>650</sup>

In late August the DHSS issued a press release: “*Date set for AIDS screening test*”, saying that John Patten had announced that screening should be introduced by mid October: the test kits under trial were the Organon and Wellcome tests.<sup>651</sup>

Screening of all donated blood finally began in the UK on 14 October 1985.<sup>652</sup>

## Commentary

If the time taken to introduce screening across the board in the UK is broken down into its constituent parts, it might be possible to provide some justification for each step: the initial proposal; the suggestion (indeed agreement) that the test should be one involving radioactive isotopes, in a form familiar to RTCs engaged in testing for Hepatitis B,<sup>653</sup> and an evaluation process, itself consisting of inviting participation, drafting and consulting on

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648 Draft preliminary report to a DHSS ad hoc group on the evaluation of commercial anti-HTLV 3/LAV assays 15 July 1985 NHBT0015169. It gave no conclusion as to which test might be best.

649 Minutes of Expert Advisory Group on AIDS meeting 30 July 1985 p3 PRSE0002628

650 Minutes of Expert Advisory Group on AIDS meeting 30 July 1985 p4 PRSE0002628, Screening of Blood Donations for Anti-HTLV III in Regional Blood Transfusion Centres DHSC6887757\_124

651 Though it said that other test kits might be evaluated in due course. Department of Health and Social Security Press Release *Date set for AIDS screening test* 23 August 1985 PRSE0002603

652 Department of Health and Social Security Press Release *All blood donations now being screened for antibodies to the AIDS virus* 14 October 1985 NHBT0004299

653 An approach which was not in the end adopted, because the trend in testing was away from the risks of using radioactive isotopes, and towards a test which was more easily scalable and producible in commercial quantities. It was the test which Wellcome wished to use so there was ultimately no reasonable alternative in any event given the limitations at BPL.



a protocol, consisting of an initial test followed by field trials, running pilot trials, reporting results and finally reaching a conclusion. However, the policy throughout was said to be that all practicable steps were being taken to ensure that the blood supply was free from the AIDS virus. At the end of 1984 and the start of 1985 there was emphasis on the urgency with which measures needed to be adopted. Viewed against this, the overall timescale – over a year from a test being developed and actually put into use to test individual patients' status<sup>654</sup> – seems inconsistent with a policy of urgency. A comparison with other countries, too, is informative: the information that Dr Smithies was able to give the CMO in May was revealing.<sup>655</sup>

What took the bulk of the time was evaluating the available tests. The concerns about a test being sensitive, but not specific, were that a large number of false positives might be produced.<sup>656</sup> That gave rise to the ethical question whether those donors whose donations had proved positive should be told of that fact. It is inescapable that this should occur. However, unless the problem of false positives was liable to create a wider problem (for instance, loss of trust in the blood donation system, leading to would-be donors no longer being willing to volunteer, leading to shortages of blood supply, in turn leading to a threat to the lives of those who depended upon the supply being maintained) it was not an acceptable reason for delay, especially where confirmatory tests were available. There was, however, little evidence that loss of trust of this type and to this scale would occur as a consequence of screening.<sup>657</sup> To suggest that it would, depended upon an assessment of human behaviour for which there was no clear empirical or other support. To argue that it might happen was also to assume that any counter measures<sup>658</sup> would have no effect. The opposite view, expressed by Professor Bloom, was that one or more of the available tests (he suggested one of those which the FDA had approved) could and should be introduced immediately to test donations. He added in a letter of 31 May that: “*Those which test as positive should be discarded and the logistics of re-testing confirmatory testing and donor counselling could*

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654 At both the Middlesex Hospital and the PHLS.

655 Letter from Dr Smithies to Dr Abrams and Dr Hunt 20 May 1985 DHSC0002269\_054. Discussed above. The information was known; the intervention of the CMO and then the Minister, John Patten, appears to have brought greater urgency.

656 The important word here is “*might*”. A letter in *The Lancet* of 2 March reported that confirmatory testing avoided this as a problem in California. Carlson et al *Letter to the Editor on HTLV III Antibody Screening of Blood Bank Donors* *The Lancet* 2 March 1985 PRSE0004824

657 There is an interesting personal recollection of how blood stocks might be managed in: Professor Dame Marcela Contreras Transcript 3 December 2021 p6 INQY1000166. “*There was a shortage of blood in the world. Not only – you know, because I had contacts and I – and because I’m foreign as well, there was a shortage of blood in the UK, nationally, and in other countries, like the USA and Europe, in European countries. And we didn’t know what to, and I said ‘Who could I call who is a public figure?’ and I thought of Princess Diana at the time, but she was too slim an [sic] I don’t think she was the right person, and I asked Prince Charles to come and donate. It took me a long time to get Buckingham Palace to allow me – for him to come, and he came [on 1 March 1985] and gave his blood at Edgware; and he was in all the newspapers, and it’s amazing how our blood stocks increased, not only in England, bu [sic] in other countries. I got letters from lots of parts in the world saying thank you, because it went round the world, this – him giving his blood, showing that he was giving his blood.*”

658 eg recruitment drives, publicity measures etc.

*then be dealt with as separate issues*".<sup>659</sup> The logic of this is compelling. Moreover, the transfusion directors had called back in July 1984 for the issue of donor counselling to be figured out, and it was plainly a manageable problem in all the countries that introduced screening and donor counselling ahead of the UK. It should not have been any reason to delay introducing screening.

There can be little criticism of the decision to evaluate tests: there was general expert agreement, underpinned by some of the results reported by the FDA before it licensed tests in March 1985, of a need for it, but there are aspects of it that took more time than was necessary. NHS Blood and Transplant ("NHSBT") submitted at the close of the Inquiry that it was "*unclear why it took around 4 months for the work of PHLS reviewing the tests to be completed*";<sup>660</sup> that "*Considering the general agreement that testing be introduced as soon as possible, it is unfortunate that the first stage of the review was not completed at an earlier stage*";<sup>661</sup> and "*Thus, on the evidence currently available there is a case for saying that the first stage of the review of the tests was slower than was necessary*".<sup>662</sup> It was right in these submissions. There has been no clear reason why an evaluation process could not have been conducted in a much shorter timescale, as was appropriate to meet the urgency of the situation. It took considerable time, not so much in the process of evaluation itself once begun, but for it to begin. The drafting of a protocol, issuing it for consideration by potential applicants (if that were done),<sup>663</sup> organising how it was to be done and then beginning to apply this process took over five months. The overall timescale, including the laboratory evaluations which then proceeded, could and should have been quicker.

This is underscored by three considerations: first, that the Wellcome and Organon test kits were introduced for universal screening on 14 October 1985, despite there having been no second stage review. This calls into question the decision to propose such a process, sure to take time, in the first place if it was to be an essential part of a "full evaluation", and suggests that the need for as full an evaluation as first proposed in the teeth of a public health crisis was overstated. The second is that when the Minister, John Patten, intervened at the end of May it appears to have injected some urgency that had been lacking, resulting in a submission and in pressure on PHLS to expedite the evaluation. The inference is the DHSS (the civil servants) were acquiescing in drift rather than demanding action.<sup>664</sup> The

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659 Letter from Professor Bloom to Dr Harris 31 May 1985 DHSC0002489\_099. He added, qualifying his view, that: "*I think that donors would readily accept withholding of all positive [sic] results as an interim measure because after all, they are themselves potential recipients.*"

660 Closing Submissions of NHSBT to the Infected Blood Inquiry p142 SUBS0000062

661 Closing Submissions of NHSBT to the Infected Blood Inquiry p142 SUBS0000062

662 Closing Submissions of NHSBT to the Infected Blood Inquiry p142 SUBS0000062

663 Letter from Dr Cash to Dr Bell 24 January 1985 p2 PRSE0004386, Letter from Dr Cash to Dr Ruthven Mitchell 25 January 1985 PRSE0001075. It is unclear if this was done. Abbott Laboratories Ltd was told it would be given the opportunity to comment, but the Inquiry has not uncovered any follow-up correspondence to suggest companies were. If, as is probable, they were not, any argument along the lines that consultation was a necessary step, and took a little time which was thus reasonably spent, falls away, leaving the overall delays even more difficult to understand.

664 I exclude the CMO from this criticism. No one at the DHSS concerned with this issue appears to have grasped the nettle of deciding that the timescale for the Tedder/Weiss test was too uncertain for matters to drift until it could be a contender for a successful evaluation until the CMO went to see

third consideration is that although the DHSS began to talk of evaluating contenders for the manufacture of a screening test in January, contemporaneous documentation shows that it continued to think that the most appropriate test was one which was in RIA format, and thus that the test which Professor Weiss and Dr Tedder had had in use was likely to be the best choice. The hope that problems with scaling up the production of such a test might be overcome given just a little time acted as a disincentive to moving quickly to evaluate the existing US candidates.<sup>665</sup> Yet (as observed above) it should have become clear earlier than it did that an RIA test was not going to be introduced. It took the CMO to establish that, and grasp the nettle of what was then to be done, in a way the DHSS officials had not. In short, the process took a few months longer than it should have done.

Next, no clear reason has been advanced to the Inquiry for not permitting and encouraging the use of one or more of the tests as an interim measure pending evaluation of the rivals, as Dr McClelland and Professor Bloom had both advocated.

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Dr Tedder, Professor Weiss and Professor Adler on 22 March 1985. Later in May, John Patten sought that someone be made responsible and accountable for completing the evaluation and delivering a test. Unfortunately, there is scant evidence of this having led to firm action immediately.

665 Some (including Abbott, whose test was not one of those favoured) suggested that testing was delayed in order to give advantage to a UK test. *The New Scientist* published an article: *Ministers delayed launch of AIDS test* New Scientist 8 August 1985 DHSC0000509. The DHSS was concerned to refute this. I do not accept there was any deliberate decision to this effect: there is no sufficient evidence of it. A more subtle process was involved. The real failure was in taking the time that was taken to realise that an RIA test was not going to be produced, by any manufacturer, and that therefore the offering from Tedder/Weiss/Wellcome was not one which had the unique advantages (as the DHSS saw it, not unreasonably given that Dr Gunson encouraged the view) of being able to slot in quickly and easily with existing practice at transfusion centres and with little need for new equipment. It was in truth simply another potential test, of the same type, and there was no point in hesitating with evaluation in order to allow it to catch up, but there was hesitation for this reason.

However, despite the CMO having said in March that it would probably be necessary for the NBTS to go ahead and use the first successful test that became available there are signs that some in the DHSS did not necessarily share his view, for Malcolm Harris (Health Services Division) sent an internal minute on 30 May 1985 saying that he expected technical evaluation of a test by Abbott to be completed by July, and “*We will then be under some pressure to complete any extra evaluation quickly.*” He then added: “*It would not be helpful to have no other choice than Abbott since their test requires special equipment. It would also be preferable to have a British test evaluated as a possible candidate. It is therefore not desirable to be precise about the timetable for testing Abbott’s test in isolation.*” Memo from Malcolm Harris to Private Office 30 May 1985 DHSC0002311\_016.

This appears to be suggesting delaying a step which might lead to early use of a commercial test in order to give advantage to a test purely because it was British. Though there is much to be said in favour of having a test made in Britain for use in Britain, this could not properly be a reason for delaying action that would help protect British lives. Nor did moving swiftly to introduce a commercial test of US manufacture logically prevent a British test being adopted later if it better suited that life-protecting purpose.

Malcolm Harris sent a memo of 2 August 1985 to Ms Bateman setting out Abbott’s complaint that the UK could have had a test in place months ago and “*we have dallied to allow the preferred UK manufacturer to catch up.*” He sought to refute that: Memo from Malcolm Harris to Ms Bateman 2 August 1985 DHSC0002116. Though I do not accept that there was any concerted, deliberate attempt to do this, the matters set out in the text and this footnote nonetheless make it more likely than not that the effect of what was said and done, and the instinctive favouring of a British product (which Malcolm Harris himself had shown) was indeed to “dally”, in part for this reason. Given the title of the *New Scientist* article, it should also be made clear that there is no evidence at all that ministers were to blame personally for any “dallying”. Quite the opposite was the case: John Patten was plainly concerned by delay, as Lord Glenarthur had been before that, and John Patten’s intervention in May gave some fresh impetus to making haste. Responsibility for dallying lay instead with the officials concerned.

As a matter of first principle, the health service of a state should strive to ensure the safety of the citizens it treats. Approaching what occurred as a matter of principle, therefore, the priority should have been to ensure blood safety. It is possible that in attempting to ensure blood safety other aspects of health are potentially affected. It is true that health, in particular, is more than merely the absence of disease, but requires a holistic assessment which includes the psychological and social health of citizens. However, the starting point must necessarily be the safety of the blood itself: and that should not give way to other considerations unless it is clear that the risks to health posed by them outweigh the risk to health posed by unsafe blood.

Taking this as the first principle, it is difficult to see any adequate justification for waiting until the evaluation of available tests ended before starting to screen blood generally, let alone taking the evaluation process at a pace which to modern eyes seems tardy and did to some at the time. The early tests might have been imprecise. There may have been shortages of supply. These may have resulted in some infected donations slipping through the net.<sup>666</sup> But so far as tests were used they would have prevented some infected donations from entering the blood supply and causing near inevitable consequences to those who eventually received those donations.

This was not a question of a drug or vaccine being given to a patient, in which situation there is an obvious risk to a patient's wellbeing if the drug or vaccine is not carefully tested in clinical trials beforehand. Almost every medicine has side-effects, the severity of which need to be assessed. This was a question of a screening test. The test was not being administered to a living patient, but to blood drawn from and tested apart from that patient. Administration of it to blood donations could do no direct harm to the recipient. There was no question of such a test encouraging risky behaviour if it proved negative.

There can be no ethical justification for not making use of available tests to screen donations as far as was possible. The policy of the Government was itself to do this, for the claim was made more than once that all practicable steps were being taken to ensure blood safety. The practice, unfortunately, did not live up to the rhetoric: there was no good reason why evaluation could not have proceeded apace alongside the application of a screening test, which if it created false positives by finding too many donations positive, would at least still prevent or reduce the entry of HIV into the blood and plasma supply.<sup>667</sup> The problems that

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666 It is to be noted that the concerns expressed were not of this – that would be a concern about “false negatives” – but rather that the tests identified too many donations as containing virus: “false positives”.

667 After this *Commentary* had been drafted, I re-read the report of the Institute of Medicine to the US DHHS – similar in the US context to the report of a public inquiry in the UK – which was set up by the DHHS to investigate “*the events leading to the transmission of HIV to individuals with hemophilia from contaminated blood products.*” It was charged with examining decisions made from 1982 through to 1986 to safeguard blood and blood products, and to evaluate the actions taken to contain the AIDS epidemic. In its report, the Committee, which consisted of 14 leading experts, said: “*In a crisis, decisionmakers may become so preoccupied with seeking solutions that will dramatically reduce danger that they will fail to implement solutions that are less effective but are likely to improve public safety to some degree. Partially effective risk-reducing improvements ... can save lives, pending the development of more efficacious safety measures.*” Institute of Medicine Committee to Study HIV Transmission Through Blood and Blood Products *HIV and the Blood Supply: An analysis of crisis*

proceeding with a test would create – whether to tell donors, the availability of confirmatory testing, any hypothetical knock-on effect on the blood donation system – were secondary. Real though these problems and considerations were, they should not have caused the delay that occurred. Blood safety should have had priority. It did not have it.

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*decisionmaking* 1995 pp5-6, p240 JREE0000019. This expresses the same criticism of inaction as set out in this paragraph, though it uses different words to express it. It provides reassurance that this expresses a general principle as to inaction and its consequences, and not simply a view reached with the benefit of hindsight.



## 5.5 Hepatitis C Screening

This chapter considers the decision-making process which led to the introduction of routine screening of blood donations for Hepatitis C in the UK, and in particular whether there were avoidable delays and whether testing should have been introduced earlier than September 1991.

### Key dates

**10 May 1988** Chiron Corporation announces identification of non-A non-B (Hepatitis C) virus.

**21 April 1989** development of the anti-HCV ELISA test announced.

**August 1989** by this date it is agreed that a decision whether and when to introduce testing will be made on a UK wide basis.

**6 November 1989** ACVSB meeting agrees to support the general introduction of the test if the FDA approves it and the pilot shows it to be “*feasible and non-problematic*”.

**November 1989** FDA grants a permit for export for diagnostic use and for research.

**17 January 1990** ACVSB decides that testing should not be introduced in advance of FDA decision.

**24 April 1990** ACVSB decides that the introduction of routine screening is not yet justified.

**2 May 1990** FDA approves anti-HCV ELISA test & US blood banks commence screening.

**2 July 1990** ACVSB approves screening in principle but recommends there should be a pilot study to decide which test is better.

**21 November 1990** ACVSB agrees screening should be started as soon as practicable – no date is proposed.

**16 January 1991** Minister approves routine screening.

**15 February 1991** Dr Gunson informs RTDs that screening will begin on 1 July.

**3 April 1991** introduction of screening postponed to 1 September 1991.

**April 1991** Dr Lloyd in Newcastle decides to begin testing unilaterally.

**1 September 1991** Screening introduced in the UK.

### People

**Dr John Barbara** lead scientist in transfusion microbiology, North London RTC

**Professor John Cash** medical and scientific director, SNBTS

**Dr Harold Gunson** director, National Blood Transfusion Service

**Gloria Hooper** Parliamentary Under-Secretary of State for Health in the Lords

**Dr Huw Lloyd** medical director, Northern Region Blood Transfusion Centre

**Dr Jeremy Metters** Deputy Chief Medical Officer

**Dr Philip Mortimer** director, Virus Reference Laboratory at PHLS

### Abbreviations

**ACVSB** Advisory Committee on the Virological Safety of Blood

**ACTTD** UK Advisory Committee on Transfusion Transmitted Diseases

**PHLS** Public Health Laboratory Service

## Introduction

The routine testing of blood donations for the Hepatitis C virus was introduced in the UK on 1 September 1991. This chapter considers the decision-making process which led to the introduction of that screening, and in particular whether there were avoidable delays and whether testing should have been introduced earlier than September 1991.

Those who have read the chapter on *Hepatitis C Surrogate Screening* will have seen an account of repeated procrastination, to the extent that decision-making was described as going round in circles; of how a desire to have the fullest information from studies of the efficacy of tests (which were continually put off, or superseded by different studies) obstructed the introduction of measures which would probably have prevented a large number of infections (even if it could not confidently be said with precision quite how many); how a seeking for the purity of “science” trumped the practicalities of securing better health – summarised as allowing “the best to become the enemy of the merely good”; and it is also an account of what might be seen as showing greater concern for donors than for recipients. In the result, nothing happened quickly enough.

Those readers may wonder whether these same themes, the same culture of decision-making and approach, and the same level of delay went on to colour the UK response to what was no longer a form of indirect test for the presence of a dangerous virus, but had become a direct test.

This chapter should provide the answer.

In doing so, there may be parts of it in which the reader wonders whether any progress was being made towards ensuring greater patient safety, and if so quite what. If so, those sections are there because, if similar conclusions to those reached in respect of surrogate screening are to be reached, it is necessary to set out “chapter and verse” – so that there is a full understanding of the Inquiry’s eventual conclusions on whether the UK approach to Hepatitis C screening fell short of what it was reasonable to expect.

With the exception of Ireland, the UK was among the last of the developed nations (if not indeed the last) to test all its blood donations directly for the presence of Hepatitis C infection: Ireland introduced it at much the same time as the UK, but in broad generalisation many countries did so 18 months to a year earlier.<sup>668</sup> Were there particular factors, other than the process of decision-making itself, which accounted for this?<sup>669</sup>

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668 See Mr Justice Burton’s timetable of when other countries commenced screening for Hepatitis C in the *Commentary at the end of this chapter*.

669 With the exception of the US and Italy, all these countries had a prevalence of Hepatitis C infection in their donor populations which was broadly of the same order of magnitude as that in the UK. The difference could thus not be accounted for by those countries having any significantly greater benefit in terms of illnesses, cirrhosis and liver cancer to avoid by using the available tests.

A good starting point to understand this issue is the judgment of Mr Justice Burton in *A and Others v National Blood Authority* in 2001.<sup>670</sup> Mr Justice Burton heard evidence from Dr Harold Gunson, who had been director of the National Blood Transfusion Service (“NBTS”), and Dr (now Professor) John Barbara, lead scientist in transfusion microbiology at the North London Blood Transfusion Centre at the relevant time, amongst other key factual and expert witnesses.<sup>671</sup> He also undertook an extensive review of the relevant literature.<sup>672</sup>

I accept Mr Justice Burton’s finding that it was generally accepted in the mid to late 1980s – and that Dr Gunson believed – that the incidence of non-A non-B Hepatitis (“NANBH”) in the UK was 3%.<sup>673</sup> This was, however, an estimate which was not based on testing directly for the causative virus (since the virus had not yet been identified), and when it could be, turned out to be to be an overestimate. A more accurate incidence was then shown. This varied from region to region but did not exceed 1%. This can be compared to the US, where it was 7-12%.<sup>674</sup> However, and in any event, it was a well-known risk.

It was also well understood at the start of the 1980s that NANBH might well be a “*serious disease with significant long-term consequences*”,<sup>675</sup> and the presence of that risk, its reality and its seriousness was established by 1986 if not earlier.<sup>676</sup> Approximately 50% of cases progressed to chronic hepatitis. It was thought that 20% of these would develop cirrhosis of the liver.<sup>677</sup>

It was plain in the light of these figures and the 3% incidence estimated by Dr Gunson both that surrogate screening should have been introduced (see the separate chapter as to this) and that if a reliable test for the virus itself could be developed, then screening should be

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- 670 *A and Others v National Blood Authority* Judgment 26 March 2001 PRSE0003333. The case was not one in which negligence was the question: it was a product liability case brought under the Consumer Protection Act. In the course of his judgment, Mr Justice Burton considered the facts in detail, and the rival cases as to the conclusions which should be drawn from them. The key points of fact which he found are set out in this chapter, and I have reached the same conclusion independently. I am not bound by his decision to do so, but I consider he was right.
- 671 *A and Others v National Blood Authority* Judgment 26 March 2001 para 87 PRSE0003333. Professor Barbara also gave evidence to this Inquiry.
- 672 *A and Others v National Blood Authority* Judgment 26 March 2001 paras 97-98 PRSE0003333
- 673 *A and Others v National Blood Authority* Judgment 26 March 2001 para 99(iv) PRSE0003333
- 674 *A and Others v National Blood Authority* Judgment 26 March 2001 para 99(iv) PRSE0003333, Dienstag and Alter *Non-A, Non-B Hepatitis: Evolving Epidemiologic and Clinical Perspective* Seminars in Liver Disease 1986 p2 PRSE0000340
- 675 That is how it was described by Dr Peter Kernoff writing to Dr Brian Colvin in April 1979 in terms similar to internal Department of Health and Social Security (“DHSS”) documents. Letter from Dr Kernoff to Dr Colvin 27 April 1979 p2 BART0002487. NANBH was described as already becoming “*a major source of concern*” in a minute about establishing an advisory group on viral hepatitis, undated but likely to be early 1980. Minute on Advisory Group on Viral Hepatitis p1 DHSC0002193\_092. “*This form of hepatitis can be rapidly fatal (particularly when acquired by patients with pre-existing liver disease) or can lead to progressive liver damage*” was Dr Diana Walford’s description in September 1980. Memo from Dr Walford to John Harley 15 September 1980 p1 WITN0282008
- 676 “*The longer patients are followed, the more obvious it becomes that CAH [chronic active hepatitis] and cirrhosis are a very real part of the natural history of NANB [non-A non-B] hepatitis.*” Dienstag and Alter *Non-A, Non-B Hepatitis: Evolving Epidemiologic and Clinical Perspective* Seminars in Liver Disease 1986 p5 PRSE0000340
- 677 Dienstag and Alter *Non-A, Non-B Hepatitis: Evolving Epidemiologic and Clinical Perspective* Seminars in Liver Disease 1986 p6 PRSE0000340

introduced. Doing so would avoid a substantial number of cases of post-transfusion hepatitis, and cases of chronic liver disease, cirrhosis, and liver cancer which would follow.<sup>678</sup>

Whether a reliable test was to be found awaited identification of the virus – long sought for, but even at the start of 1988 not yet achieved.

## Development of the Chiron/Ortho test

On 10 May 1988, the Chiron Corporation in California (“Chiron”) announced that it had cloned a protein of the blood-borne non-A non-B Hepatitis virus.<sup>679</sup> Identification of the virus made it possible that a test to screen blood for non-A non-B Hepatitis could be developed. In its announcement, Chiron stated that it had a prototype immunoassay which was expected to lead to a screening test, which would be marketed by Ortho Diagnostic Systems (“Ortho”). It was reported that Chiron hoped to have the test available for clinical trials by the end of the year.<sup>680</sup>

The newly identified virus was named Hepatitis C.

The development was noted in the UK. On 29 June 1988, the Working Group on Plasma Fractions, with membership drawn from the National Institute for Biological Standards and Control (“NIBSC”), the Protein Fractionation Centre (“PFC”) and the Blood Products Laboratory (“BPL”), met. The minutes record that, “*Evidence of the value of the Chiron test for non-A non-B hepatitis is not yet available in this country. Future developments will be watched with much interest.*”<sup>681</sup>

On 5 July 1988, Professor John Cash of the Scottish National Blood Transfusion Service (“SNBTS”) wrote two letters in response to the reported new development. He asked

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678 Though the article came later than the date Mr Justice Burton identified as an appropriate starting date, a reasonable idea of the scale of illness that was preventable (and would have been realised to be preventable) was given in a 1991 paper in *Reviews in Medical Virology*. This estimated that the introduction of Hepatitis C screening in the UK would prevent between 2,500 and 5,000 cases of post-transfusion hepatitis per year, between 1,250 and 2,500 cases of chronic liver disease per year and 250 to 500 cases of cirrhosis per year. Brown and Thomas *Blood Transfusion Services Should Have Begun Screening for Hepatitis C When an Antibody Assay First Became Available* *Reviews in Medical Virology* 1991 NHBTO088770. Dr Barbara put the counterargument in the same journal article. As a second point, the incidence of NANBH/Hepatitis C which Dr Gunson took as his starting point would inevitably fall to be reviewed once tests were possible, for it would then be more accurately known what the prevalence of Hepatitis C was in the donor population. However, the article just mentioned took a figure of 0.5-1%. Dr Gunson’s figure prior to the cloning of Hepatitis C virus by the Chiron Corporation was some four times greater. The figure he reached by October 1989 after experience in pilot tests with the Chiron/Ortho test was that overall prevalence seemed to be 0.77%: a quarter of the figure he had assumed earlier, but in line with estimates by Dr Jennifer Brown and Professor Howard Thomas. Letter from Dr Gunson to Graham Hart 2 October 1989 p2 NHBTO000188\_056. The number of preventable cases is obviously still significant.

679 Chiron Press Release *Chiron Clones Hepatitis Non-A, Non-B Virus Which May Allow Screening for Previously Undetectable Disease* 10 May 1988 PRSE0000842. The Chiron announcement noted that according to National Institutes of Health estimates, prior to 1986, up to 10% of those receiving blood transfusions in the US were infected with NANBH, 50% of whom developed chronic hepatitis. Of the latter group, 20% developed cirrhosis of the liver.

680 American Association of Blood Banks *Hepatitis Non-A, Non-B Virus Discovered* Blood Bank Week 13 May 1988 p1 PRSE0003126

681 Minutes of Working Group on Plasma Fractions meeting 29 June 1988 p2 NHBTO007576

Dr Ginger Rosenberg at Chiron for access in due course to antibody testing kits for evaluation purposes.<sup>682</sup> He also wrote to the UK branch of Ortho, Ortho Diagnostic Systems Ltd, asking for confirmation that they would be marketing the new test and “*some idea of the current time schedule to the point of full marketing in the UK for full donation testing.*”<sup>683</sup> The marketing director replied that the product might be available towards the end of 1989, but there was a great deal of work to do regarding manufacturing and trials to get to that point.<sup>684</sup>

The date of May 1988 is important for what follows. Once it was announced, it was clear that an effective screening test was likely to be available soon. It was probable that it would be introduced as universal screening. Preparations for this could start immediately. They did not have to wait for the test to be produced. Any issues of principle could be sorted out beforehand. Since the purpose of any such test was to identify as many infected donations as possible, what donors of those units should be told needed to be settled. How best to confirm that the donation was or was not infected so that the implicated donor could be given the most reliable information of their infective status would need to be resolved. Further, it could be foreseen that when an acceptable test emerged, finance to implement it without any harmful delay would need to be in place. Steps to deal with all these issues could have been taken from May 1988 onwards.

On 11 October 1988, Dr Gunson and Dr Barbara travelled to meet Chiron representatives in Kansas City. They discussed the test under development and were told that clinical trials would soon begin. They agreed to conduct a UK study, with 1,000 samples to be sent from the UK to Chiron for blind testing.<sup>685</sup>

In December 1988, Dr Barbara wrote in the *Transfusion Microbiology* newsletter that Chiron’s achievement in isolating the non-A non-B Hepatitis antigen appeared to have borne fruit in the shape of a new enzyme-linked immunosorbent assay (“ELISA”) test for the anti-HCV antibody. Samples from two donors at the North London Blood Transfusion Centre whose donations were implicated in transmitting non-A non-B Hepatitis had tested positive when blind tested in a panel by Chiron.<sup>686</sup>

The development of the anti-HCV ELISA was then announced on 21 April 1989 in the journal *Science*. It was reported that a blind panel study had shown that the new test had a high level of sensitivity and specificity, with positive results usually appearing in three to six months after the transfusion believed to have caused the infection. The article concluded that, “*The*

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682 Letter from Professor Cash to Dr Rosenberg 5 July 1988 PRSE0000670

683 Letter from Professor Cash to Allan Follett 5 July 1988 PRSE0002363

684 Letter from Allan Follett to Professor Cash 25 July 1988 PRSE0002112

685 Note of NBTS and Chiron meeting 11 October 1988 NHBT0000014\_023. Dr Gunson reported the agreement to a meeting of the SNBTS directors on 13 December 1988. Minutes of SNBTS Directors meeting 13 December 1988 p4 PRSE0001626. He wrote to the Department of Health about it on 6 January 1989. Letter from Dr Gunson to Dr M E Smith 6 January 1989 p1 NHBT0000014\_033

686 Barbara A *Specific Test for Non-A, Non-B Hepatitis?: Some Answers, More Questions* Transfusion Microbiology Newsletter Number 9 December 1988 p2 NHBT0000030\_030



*advent of the specific, sensitive test for HCV antibody described here should improve the safety of the world's blood supply as well as provide an important clinical diagnostic tool.”*<sup>687</sup>

The date of 21 April 1989 is thus the second significant milestone date.

### **Initial concerns over introducing Hepatitis C testing in the UK**

The identification of Hepatitis C and the fact that a test for it was under development by Chiron/Ortho gave rise to concerns in some quarters over the implications for blood donation systems in the UK.<sup>688</sup>

Thus in November 1988, before the development of a marketable test, Dr Barbara and Dr (later Professor Dame) Marcela Contreras wrote to Dr Harvey Alter at the National Institutes of Health querying his support for the implementation of anti-HCV testing: “*You stated that it would be unethical to delay anti-HCV screening pending a prospective study of the current incidence of NANB PTH [non-A non-B post-transfusion hepatitis] in the USA. However in your discussion and in the literature we have been unable to find any data to support urgent initiation of anti-HCV testing in addition to surrogate screening.*”<sup>689</sup> They queried the evidence for a causal association of transfusion with cases of cirrhosis studied by Dr Alter, and went on:

*“In any case, in the UK with a low prevalence of NANB PTH and a relatively high prevalence of high ALT [alanine transaminase] and anti-HBc in blood donors you may agree that it would not be sensible to spend millions of pounds in preventing a relatively small number of cases of NANB PTH when the money could be more effectively used in other areas of our Health Service? Currently we appear to have less post-transfusion NANBH without any form of donor screening than the USA does even after surrogate testing!”*<sup>690</sup>

In his December 1988 article in *Transfusion Microbiology*, Dr Barbara repeated similar doubts. Whilst recognising that the Chiron/Ortho ELISA test was likely to be specific and sensitive for anti-HCV, he noted that it would not detect the virus in the period between infection and development of the antibody, and so plasma pooling would still represent a risk. He stated that “*the rate of post-transfusion NANBH in the UK is extremely low and the contribution of post-transfusion NANBH to chronic hepatitis in the UK remains to be*

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687 Kuo et al *An Assay for Circulating Antibodies to a Major Etiologic Virus of Human Non-A, Non-B Hepatitis* Science 21 April 1989 pp4-6 BAYP0000012\_094. The same journal volume also included an article on the cloning of Hepatitis C: Choo et al *Isolation of a cDNA Clone Derived from a Blood-Borne Non-A, Non-B Viral Hepatitis Genome* Science 21 April 1989 pp1-4 BAYP0000012\_094

688 There were, in effect, two questions: should there be a universal screening test for Hepatitis C; and if so, what needed to be done to provide for it. The early discussion reported here focussed more on the first of these twin questions than the second.

689 Letter from Dr Contreras and Dr Barbara to Dr Alter 15 November 1988 p1 NHBT0000187\_032

690 Letter from Dr Contreras and Dr Barbara to Dr Alter 15 November 1988 pp1-2 NHBT0000187\_032

*confirmed*". His view was that it remained to be seen whether the new test would gain acceptance as a blood donor screening assay.<sup>691</sup>

On 15 January 1989, Dr Contreras wrote to Dr Gunson asking whether central funding for anti-HCV screening would be provided by the Department of Health. She indicated that she did not consider it to be a top priority for the regional budget in comparison with reducing waiting lists, and that it would be very difficult, if not impossible, to find the funding within existing resources.<sup>692</sup>

### **NBTS and SNBTS trials of the Chiron test**

Ortho test kits were to be supplied to the North London Blood Transfusion Centre to undertake a trial on behalf of the National Blood Transfusion Service. Dr Barbara met Peter Savage of Ortho on 14 March 1989 to discuss this arrangement. They agreed that samples taken for the purposes of a three-centre study<sup>693</sup> into surrogate markers alanine transaminase ("ALT") and Hepatitis B core antibody ("anti-HBc")<sup>694</sup> would be made available for testing with the Chiron/Ortho ELISA test. Ortho agreed to provide 10,000 test kits, superseding the previous arrangement for 1,000 samples to be tested by Chiron. They also agreed to undertake anti-HCV testing on samples deriving from local studies at the North London Blood Transfusion Centre. Dr Barbara drafted the relevant protocols for discussion at a further meeting on 29 March 1989.<sup>695</sup>

On 31 March 1989, Professor Cash wrote to Dr Gunson asking whether Dr Barbara might be persuaded to include SNBTS samples which had been tested for ALT in the North London Blood Transfusion Centre anti-HCV screening trial.<sup>696</sup>

Additionally, on 20 April 1989, Dr Charles Rizza wrote to all haemophilia centre directors that Ortho were expected to supply test kits "*for the non A non B marker, anti hepatitis virus C*" to the Public Health Laboratory Service ("PHLS") at Colindale, sufficient to test "*several hundred haemophiliacs*".<sup>697</sup>

It was then, in April 1989, that details of the test were published.<sup>698</sup>

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691 Barbara A *Specific Test for Non-A, Non-B Hepatitis?: Some Answers, More Questions* Transfusion Microbiology Newsletter Number 9 December 1988 p2 NHBT0000030\_030

692 Letter from Dr Contreras to Dr Gunson 15 January 1989 NHBT0000187\_042

693 North London, Manchester and Bristol.

694 See the Chapter on *Hepatitis C Surrogate Screening*.

695 Dr Gunson and Dr Contreras also attended the 29 March 1989 meeting. Report by Dr Barbara: Anti-HCV Screening with Ortho ELISA 21 March 1989 NHBT0000014\_041. See also: Written Statement of Dr Harold Gunson in *A and Others v National Blood Authority* p30 NHBT0000026\_009. On 13 April 1989, Peter Savage met Dr Barbara again and further details were agreed. Minutes of North London Blood Transfusion Centre meeting 13 April 1989 NHBT0000187\_061

696 Letter from Professor Cash to Dr Gunson 31 March 1989 NHBT0000014\_044

697 Dr Rizza relayed that Dr Philip Mortimer of PHLS was intending to conduct a study and keen to receive sera from patients known to have received only NHS product, and only 8Y NHS product. Letter from Dr Rizza to all UK haemophilia centre directors 20 April 1989 GGCL0000033\_001

698 Kuo et al *An Assay for Circulating Antibodies to a Major Etiologic Virus of Human Non-A, Non-B Hepatitis* Science 21 April 1989 pp4-6 BAYP0000012\_094

A preliminary report dated 23 June 1989 showed that as at that date 3,282 samples screened for ALT and anti-HBc in the NBTS three-centre study had been tested using the first-generation Chiron/Ortho ELISA test. There were 22 initial reactive and 14 repeat reactive samples using Ortho’s criteria, but 2 further samples were noted to be reactive below the stipulated threshold. The test was considered to be “*reproducible, robust and meaningful*”, albeit further study was required.<sup>699</sup>

Professor Cash’s wish to include SNBTS samples in the North London Blood Transfusion Centre Chiron/Ortho trial was not granted. Instead, in June 1989, Professor Cash arranged with Ortho to obtain kits for the SNBTS to evaluate. It was agreed that the West of Scotland Blood Transfusion Service would carry out the evaluation.<sup>700</sup> Professor Cash wrote to Dr Gunson on 10 July 1989 to tell him that he was organising a separate test.<sup>701</sup>

Dr Gunson reported the preliminary findings of the NBTS three-centre study to the First International Meeting on the Hepatitis C Virus in Rome on 14-15 September 1989. The data showed that 11 of 3,032 samples from Bristol (0.36%), 25 of 3,642 samples from Manchester (0.69%) and 25 of 3,010 samples from North London (0.83%) repeatedly tested positive for anti-HCV.<sup>702</sup>

As Professor Cash had arranged, the SNBTS regional transfusion centres (“RTCs”) submitted 2,745 randomly selected blood donor samples for testing, which was carried out from August 1989.<sup>703</sup> A preliminary report on the “*SNBTS Evaluation of the Ortho HCV Antibody ELISA Test System*” was produced by Dr Brian Dow, Dr Ruthven Mitchell and Archie Barr in October 1989. Of the samples submitted, 15 initially screened as positive and 13 were repeatedly reactive (0.47%, or roughly 1 in 200).<sup>704</sup> The study also looked at transfusion recipients, and found that 1 in 33 multi-transfused patients screened positive

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699 HCV Assay Preliminary Report No.2 23 June 1989 p1, p4 NHBT0000017\_006

700 SNBTS Evaluation of the Ortho HCV Antibody Elisa Test System Preliminary Report 5 October 1989 p2, p5 NHBT0000072\_038

701 “*We have decided that it is important for the SNBTS to look at the prevalence of Chiron test positives in our donor community and I write to let you know that we intend to look at approximately 5,000 donations. The donations which will be selected will be those we have already got ALT data on. We’ll keep you informed of the outcome of this study.*” Dr Gunson replied on 26 July 1989: “*I am pleased that you are carrying out 5000 tests for anti-HCV. John Barbara has now almost completed the tests on the 9000 from England and when the results are to hand I will send them to you.*” Letter from Professor Cash to Dr Gunson 10 July 1989 NHBT0000188\_006, Letter from Dr Gunson to Professor Cash 26 July 1989 NHBT0000076\_003

702 Report on the Meeting in Rome to Discuss Chiron Testing 10 October 1989 p9 DHSC0003557\_053; by Dr Gunson to the Advisory Committee on Transfusion Transmitted Diseases (“ACTTD”). A final report on the three-centre study was published in April 1990: Multi-Centre UK NANB Surrogate Marker Study Report April 1990 PRSE0000290

703 SNBTS Evaluation of the Ortho HCV Antibody Elisa Test System Preliminary Report 5 October 1989 p2 NHBT0000072\_038

704 SNBTS Evaluation of the Ortho HCV Antibody Elisa Test System Preliminary Report 5 October 1989 p5 NHBT0000072\_038. The ALT levels of all the samples had previously been checked; only one of the anti-HCV positive samples had shown an abnormal ALT level. The initial screen positives from Dundee and Glasgow were also tested for anti-HBc, and none were reactive for anti-HBc.

(3%).<sup>705</sup> 92 of 146 people with haemophilia from the West of Scotland whose samples were tested were shown to be repeatedly reactive for anti-HCV (63%).<sup>706</sup>

The report concluded that the Chiron/Ortho test had an acceptable specificity but there were concerns about its sensitivity.<sup>707</sup>

## The Advisory Committee on the Virological Safety of Blood and the Advisory Committee on Transfusion Transmitted Diseases

While evaluation of the Chiron/Ortho test for Hepatitis C was taking place both in England and in Scotland, and before the results mentioned above were reported, a new body was being set up to give advice on the necessary steps for ensuring the virological safety of blood in the UK. A need for this had been the subject of a memo circulated in July 1988 by Dr Edmund Harris, Deputy Chief Medical Officer.<sup>708</sup> The infections on which advice would be sought included non-A non-B Hepatitis, in relation to which Dr Harris wrote that there was “*no direct marker at present; dispute ove [sic] indirect markers. No routine testing now.*”<sup>709</sup> It may be inferred that he had not followed the news of the Chiron development, though some three months had passed since the announcement that it had identified the virus.

The new body was in due course established, named the Advisory Committee on the Virological Safety of Blood (“ACVSB”).<sup>710</sup>

While the Department of Health was in the process of setting up the ACVSB, the National Directorate of the NBTS established a UK Advisory Committee on Transfusion Transmitted Diseases (“ACTTD”), with a view to providing advice to the Government specifically regarding transfusion transmitted diseases. It met earlier than the ACVSB, first on 24 February 1989, when Dr Gunson was elected chair. He reported to the meeting that Ortho had approached him with respect to trials of the Chiron test in the UK, and that he would report on this later when further details were available.<sup>711</sup>

705 SNBTS Evaluation of the Ortho HCV Antibody Elisa Test System Preliminary Report 5 October 1989 pp18-19 NHBT0000072\_038

706 SNBTS Evaluation of the Ortho HCV Antibody Elisa Test System Preliminary Report 5 October 1989 pp18-19 NHBT0000072\_038

707 SNBTS Evaluation of the Ortho HCV Antibody Elisa Test System Preliminary Report 5 October 1989 p30 NHBT0000072\_038. In other words, it would give few false negative results, but would not necessarily catch all the positive cases.

708 On 14 July 1988, Dr Harris (Deputy Chief Medical Officer, England) sent a minute to various officials, including representatives from the Welsh Office, DHSS Northern Ireland and Scottish Home and Health Department, discussing the need for such a body. The minute explained that this issue had arisen at the last Expert Advisory Group on AIDS (“EAGA”) meeting, which concluded that EAGA was not the appropriate body since it was concerned with AIDS, and viruses other than HIV were transmitted by blood. Memo from Dr Harris on Virological Safety of Blood 14 July 1988 DHSC0003597\_133

709 Memo from Dr Harris on Virological Safety of Blood 14 July 1988 p2 DHSC0003597\_133

710 As to whether the ACVSB or a similar body should have been established earlier, see the chapter on *Role of Government: Response to Risk*.

711 Minutes of ACTTD meeting 24 February 1989 p1, p4 NHBT0000043\_002

The ACVSB met for the first time on 4 April 1989, chaired by Dr Harris the Deputy Chief Medical Officer. Dr Harris emphasised to those attending that their advice on the subjects under discussion could be “*publicly sensitive*” and should not be discussed outside the ACVSB “*unless specifically indicated*.”<sup>712</sup> The ACVSB’s role was to give advice to the UK health ministers. Its concern would be “*the major policy issues*”, with the implementation of the policy being for others.<sup>713</sup> The issue of anti-HCV testing was not covered, but it was noted that the next meeting should concentrate on viral hepatitis.

Accordingly, on 12 May 1989, Dr Andrzej Rejman and John Canavan at the Department of Health wrote to all members of the ACVSB enclosing a paper from Dr Philip Mortimer of PHLS entitled *Non-A, Non-B Hepatitis*.<sup>714</sup> In his paper, Dr Mortimer reported on the development of the Chiron test. He also referred to the United Kingdom Blood Transfusion Services (“UKBTS”) surrogate testing study and noted that, “*Although there is no UK experience of the Chiron test, arrangements have been made by UKBTS for 10,000 tests, to allow testing of the donors in the NANB [non-A non-B Hepatitis] study*.” His recommendation to the ACVSB focused on surrogate testing, suggesting that there was no urgent need to introduce it but that this position should be reconsidered by the ACVSB when the results of the UKBTS study were available. He observed, however, that “*The Chiron test may also make surrogate testing obsolete, provided that the UKBTS and other studies confirm the promising results so far reported, and assuming that the cost benefit analysis is satisfactory*.”<sup>715</sup>

On the same day, Dr Richard Lane (BPL) wrote to Dr Rejman attaching a paper for consideration at the next ACVSB meeting entitled *The fractionator’s view of limitation of transmission of hepatitis viruses in plasma products*. He wrote that:

*“Prevention of transmission of hepatitis by plasma products is in accordance with the general philosophy of the Blood Transfusion Service whereby care to limit risk of transmitted infection is exercised at every opportunity as opposed to dependence on a single finite step to eliminate or inactivate virus.*

*Thus, general fractionation policy includes quality procedures which commence with donor selection and blood donation and extend through processing to*

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712 Dr Pickles said that the expectation at the time was that papers for medical advisory committees would not be disseminated or shared outside the committee. Written Statement of Dr Hilary Pickles para 18.1 WITN6965001

713 Minutes of ACVSB meeting 4 April 1989 p1 NHBT0000041\_003. The other members of the ACVSB as at that date were Dr Lane (BPL), Dr Mortimer (PHLS), Dr Robert Perry (PFC), Dr Geoffrey Summerfield (consultant haematologist), Professor Arie Zuckerman, and Dr Philip Minor (NIBSC). The secretariat was Dr Rejman and John Canavan, both of the Department of Health. Various observers attended, including Dr Hilary Flett (DHSS, Northern Ireland), Dr Alain George (Welsh Office) and Dr Archibald McIntyre (Scottish Home and Health Department).

714 Memo from Dr Rejman and John Canavan to all members of the ACVSB 12 May 1989 NHBT0000061\_022. Dr Rejman was a senior medical officer within the Department of Health, with responsibility for haematology and blood transfusion; John Canavan was a Principal grade civil servant within the Health Services Division, Branch 1, Division A (“HS1A”) of the Department of Health (an administrative division with responsibility for a number of health services, including blood transfusion).

715 Memo from Dr Rejman and John Canavan to all members of the ACVSB 12 May 1989 pp2-3 NHBT0000061\_022



*quality control and release of finished products and incorporate requirements to minimise virus transmission wherever possible.”*<sup>716</sup>

He referred to the three-centre UKBTS study, which gave “*an opportunity to test the correlation between marginal or raised levels of ALT in plasma and the presence of antibody to HCV using the new Chiron marker immune assay.*”<sup>717</sup> He stated that an early review of this data would be of considerable importance to decisions on the future testing programme for blood donations and plasma for fractionation, noting that the initial reports from the US indicated good correlation between the results of the Hepatitis C test and selected reference panels of donor and patient sera, and went on to conclude that:

*“There is an urgent requirement to address the requirements for a marker to identify NANBH (HCV) carrier status. While it is hoped that a marker for HCV will be introduced in the near future, it is probable that a risk of transmission of other viral agents implicated in NANBH will remain”*<sup>718</sup>. *On initial enquiry, it seems likely that the commercial fractionators will retain ALT-screening of plasma to augment the specific HCV marker results.”*<sup>719</sup>

The ACTTD met for the second time on 19 May 1989, again before the ACVSB. Dr Barbara gave an oral report on the progress that had been made in anti-HCV testing samples from the three-centre surrogate marker trial. He stated that 400 samples per day were being processed and the test was running “*consistently with the manufacturer’s expectations*” but that it was a “*considerable drain on resources.*”<sup>720</sup>

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716 The Fractionator’s View of Limitation of Transmission of Hepatitis Viruses in Plasma Products 12 May 1989 p2 NHBT0000187\_069

717 The Fractionator’s View of Limitation of Transmission of Hepatitis Viruses in Plasma Products 12 May 1989 pp3-4 NHBT0000187\_069

718 It was unknown whether NANBH was caused by one or more viruses. Given the experience that the isolation of Hepatitis B virus had shown that it was not on its own the cause of serum hepatitis, it was not unreasonably supposed that there may be more than one other principal virus involved.

719 The Fractionator’s View of Limitation of Transmission of Hepatitis Viruses in Plasma Products 12 May 1989 p6 NHBT0000187\_069

720 Minutes of ACTTD meeting 14 May 1989 pp3-4 NHBT0000088\_001. Professor Cash reported that the SNBTS would be interested in taking part in trialling the Chiron test, using the bank of samples already tested for ALT. Professor Cash went on to pursue this goal, writing to Dr Christopher Ludlam at the Royal Infirmary Edinburgh on 16 June 1989, “*We (SNBTS) hope to have restricted access to the Chiron (NANB) testing kits and I write to enquire whether you would be prepared to let us have serum samples from your haemophilia patients?*” Letter from Professor Cash to Dr Ludlam 16 June 1989 SBTS0000155\_095. He wrote to Dr William Whitrow (Inverness), Dr Stan Urbaniak (Aberdeen) and Dr Ewa Brookes (Dundee) on similar terms on the same day. This initiative resulted in the test referred to above, which began in August. Letter from Professor Cash to Dr Whitrow, Dr Urbaniak and Dr Brookes 16 June 1989 SBTS0000365\_016, SNBTS Evaluation of the Ortho HCV Antibody Elisa Test System Preliminary Report October 1989 p2 NHBT0000072\_038

The ACVSB held its second meeting on 22 May 1989.<sup>721</sup> The papers circulated included Dr Mortimer’s report<sup>722</sup> and Dr Lane’s paper<sup>723</sup> mentioned above. The minutes state:

*“Members advised that although colleagues in the US considered only one virus caused NANB, there may be two or more. The Chiron test was estimated to pick up approximately 50% only<sup>724</sup> and there was a need for caution. There had been enormous progress and once the sequence was published it would be possible to test without recourse to Chiron.”*<sup>725</sup>

It was agreed that testing blood donations for non-A non-B Hepatitis (by either surrogate or Chiron tests) should not be introduced until after the UKBTS trial had been completed, and that: *“The Department would keep the issue of testing under review. The use of Chiron or surrogate testing would be influenced by Chiron data once released; MRC [the Medical Research Council] might be asked to consider. Members regarded the matter to be a priority.”*<sup>726</sup>

The third ACVSB meeting took place on 3 July 1989.<sup>727</sup> Dr Gunson tabled a paper on non-A non-B Hepatitis screening in ten other countries. This survey showed that Denmark, Sweden and Finland were trialling the Chiron/Ortho anti-HCV test, and several other countries were planning to do so.<sup>728</sup> Dr Gunson also presented the preliminary report on the UKBTS study of surrogate and Chiron testing.<sup>729</sup> The minutes noted:

*“The Chiron test had been used in first time recipients of Factor 8Y. Preliminary results had shown no positives, while most recipients of earlier concentrates were Chiron positive. Further study of stored haemophilic sera was advocated. Dr Mortimer had attended a recent conference, and he considered the findings represented a persuasive case that the Chiron test results were reliable. The Chairman therefore considered that a compilation of all the data should be given to the Committee for consideration at the next meeting. Members were asked to forward all contribution [sic] on NANB to Dr Rejman.”*<sup>730</sup>

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721 In addition to the members represented at the first meeting, Dr (now Professor) Richard Tedder, Dr (now Professor) Edward Tuddenham and Dr Mitchell were also present.

722 Memo from Dr Rejman and John Canavan to all members of the ACVSB 12 May 1989 NHBT0000061\_022

723 The Fractionator’s View of Limitation of Transmission of Hepatitis Viruses in Plasma Products 12 May 1989 NHBT0000187\_069

724 This picked up on the question of the sensitivity of the test, views augmented later in the autumn by the results from the three-centre study (England) and the SNBTS study (Scotland).

725 Minutes of ACVSB meeting 22 May 1989 p3 NHBT0005019

726 Minutes of ACVSB meeting 22 May 1989 p3 NHBT0005019

727 This was the last ACVSB meeting chaired by Dr Harris; Dr Jeremy Metters, his successor as Deputy Chief Medical Officer, took over as ACVSB chair from 1 August 1989.

728 Analysis of Replies to Questionnaire on Non-A, Non-B Hepatitis 1989 pp2-3 NHBT0000041\_051

729 Chairman’s Brief of ACVSB meeting 3 July 1989 p2 NHBT0000061\_031, HCV Assay Preliminary Report No.2 23 June 1989 NHBT0000017\_006

730 Minutes of ACVSB meeting 3 July 1989 pp2-3 NHBT0000072\_025

## Proposals for a united UK-wide approach to introducing anti-HCV testing

In a letter of 26 July 1989 to Professor Cash about the SNBTS evaluation, Dr Gunson wrote:

*“I am having some difficulties with Ortho who are wanting to know when (not if) we are going to introduce routine testing and how many tests we wish to order. There is a meeting in Rome on 14th/15th September 1989 and Marcela,<sup>731</sup> John<sup>732</sup> and I are attending. If you have not had an invitation I think you should secure one. The intention of the meeting is to review the European experience with the test.*

*My view is that we should not move until we know what our European colleagues are doing. For the U.K. it is important that the SNBTS and the NBTS act in close collaboration since I can foresee difficulties if one of us introduced the test unilaterally. I hope we can discuss this matter soon.”<sup>733</sup>*

Professor Cash replied straight away that close collaboration seemed certain, since the SNBTS would not move unilaterally unless instructed to do so by the Scottish Home and Health Department (“SHHD”). He reassured Dr Gunson that he had indicated to Ortho that the SNBTS would not be able to discuss contracts for supply of the test kits unless instructed to do so by “our Department of Health”.<sup>734</sup>

On the same day, Professor Cash wrote to Dr Archibald McIntyre at the SHHD, setting out his record of a telephone conversation they had had the previous week:

*“You indicated that the decision to commence routine donation testing, using the Ortho (Chiron) test, throughout the SNBTS, would be made by SHHD, and that it would not be appropriate at this time for senior SNBTS managers to liaise with Ortho Ltd with respect to arranging supplies of tests for routine donation testing. Such discussions should not take place until instructions are received from SHHD. I’d be most grateful if you would confirm this position.”<sup>735</sup>*

Before replying to Professor Cash, Dr McIntyre spoke to Dr Jeremy Metters<sup>736</sup> and Dr Rejman at the Department of Health. Dr Rejman confirmed that the decision would be taken on a UK-wide basis and told him that “the ACVSB had decided that at present NANB was not to be screened for as a routine.”<sup>737</sup> Dr McIntyre replied to Professor Cash that the ACVSB was considering the tests available and if it were thought to be desirable to introduce further routine screening, “this will be done simultaneously throughout the UK”.<sup>738</sup> Professor Cash

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731 Dr Contreras.

732 Dr Barbara.

733 Letter from Dr Gunson to Professor Cash 26 July 1989 NHBT0000076\_003

734 Letter from Professor Cash to Dr Gunson 28 July 1989 NHBT0000188\_011

735 Letter from Professor Cash to Dr McIntyre 28 July 1989 p1 SBTS0000365\_022

736 Deputy Chief Medical Officer, England.

737 Memo from Dr Rejman to Dr Jones 3 August 1989 p1 NHBT0000061\_035

738 Letter from Dr McIntyre to Professor Cash 2 August 1989 NHBT0000061\_034

wrote back on 4 August 1989 to say that he had spoken to Peter Savage at Ortho, and advised him that the ACVSB would be the key group in the decision-making process.<sup>739</sup>

Dr Rejman also noted a conversation he had had with Dr Gunson, who intended to report at the October meeting of ACVSB on both the results of a pilot study of 10,000 samples in London, due in October, and a review of the European experience of Chiron testing which was to be discussed in Rome in mid September.<sup>740</sup> Dr Rejman had also heard that the PHLs (Dr Mortimer) was soon to publish the results of their experience of Chiron testing of presumed non-A non-B Hepatitis samples, and would be making a recommendation for use of this test in this publication.<sup>741</sup>

Also on 3 August 1989, Professor Cash wrote to the SNBTS directors with an update regarding Chiron/Ortho testing: *“I now believe that it is only a matter of time before we commence this new testing programme. Whilst I have no idea when we will start I’d back the horse with ‘sometime after April 1990’ on its nose!”*. He explained that the decision to implement testing would be made by the UK Departments of Health, as would the decision as to when to start, albeit in consultation with the UKBTS directors.<sup>742</sup>

The next day he recorded that he had met Peter Savage of Ortho. Professor Cash had raised with him the need for confirmation testing, and for it to be in British hands. He advised Dr McIntyre of the SHHD that the UK should let it be known that a decision whether to introduce Chiron testing throughout the UK Blood Transfusion Service (“BTS”) would be made at *“the special meeting to be held on 17th October 1989.”*<sup>743</sup>

By August, therefore, the powerful voices of Professor Cash and Dr Mortimer were leaning in the direction of recommending universal testing for Hepatitis C in the near future. On

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739 Letter from Professor Cash to Dr McIntyre 4 August 1989 NHBT0000188\_016. Professor Cash had also pressed Peter Savage for more information about confirmation testing; Ortho’s proposal at that time was to send samples to the US for confirmation testing, which Professor Cash thought unacceptable.

740 *“Dr Gunson had discussed the Chiron test with Ortho and had explained to them that the decision on routine Chiron testing would be made by the ACVSB. He had also stressed his anxiety that the Chiron test took three and a half hours which was not very practical when blood components (such as platelets) might need to be used on the same day as they had been donated. In addition there was no confirmatory test available and reliance had to be placed on repeated positivity. This might lead to the loss of a lot of falsely positive donors, if the situation is anything similar to HIV in the early days of testing. (HIV testing takes just over two hours and the extra hour and a half is very significant).”* Memo from Dr Rejman to Dr Jones 3 August 1989 p1 NHBT0000061\_035

741 He had heard this from the Procurement Division. He told this to Dr Gunson who responded that: *“this would be very unhelpful to DH [Department of Health], and he hoped that Dr Mortimer who is a member of ACVSB would be sensible”*. Memo from Dr Rejman to Dr Jones 3 August 1989 p2 NHBT0000061\_035. Dr Rejman commented on this in his evidence. Dr Andrzej Rejman Transcript 11 May 2022 pp87-93 INQY1000204. Dr Gunson’s concerns may have been influenced by a letter of 25 July 1989 from Dr Contreras and Dr Barbara. They wrote to Dr Gunson saying that *“Before we submit to pressure for placing firm orders for routine donor screening with the new anti-HCV assay, we feel that there are several issues that need to be addressed.”* They referred to the need for preliminary studies to be further extended and analysed, the time required to perform the assay, the need for a confirmatory test, the potential loss of donors, and other perceived practical obstacles, including that *“Counselling will be prohibitively costly and a logistical nightmare!”* Letter from Dr Contreras to Dr Gunson 25 July 1989 p1 NHBT0000188\_009

742 Letter from Professor Cash to SNBTS Directors 3 August 1989 NHBT0000188\_014

743 Letter from Professor Cash to Dr McIntyre 4 August 1989 p2 NHBT0000188\_016

18 August 1989, Dr Gunson wrote to all the regional transfusion directors in England and Wales, and to Professor Cash of the SNBTS:

*“It is important that we act in a co-ordinated manner nationally and also with Scotland with the introduction of these tests<sup>744</sup> with respect to the routine screening of donations. There will have to be approval of the DH [Department of Health] before they are introduced and the means for obtaining this is the agreement of the DH’s Committee on the Virological Safety of Blood. This meets next on 17th October 1989 ... Anti-HCV is being evaluated currently in the North London and the Glasgow and West of Scotland RTCs. There are many aspects to clarify before routine testing can commence, although I think it would be prudent to include the cost of this test as a development in your budgets for 1990/91. Currently I have been quoted £1.50 per test. Other aspects are the availability of confirmatory tests and the counselling and replacement of donors found positive. Preliminary results suggest that positives may be in the region of 0.5 to 1.0% although there may be regional variations.”<sup>745</sup>*

Accordingly, the position by late August 1989 was that it was agreed that any decision whether, and when, to implement a screening test for non-A non-B Hepatitis would be made on a UK-wide basis, following a recommendation by the ACVSB which was due to discuss the issue at its forthcoming meeting of 17 October 1989. However, the indications were that the SNBTS (Professor Cash) and PHLs (Dr Mortimer) would favour it, and that Dr Gunson anticipated the introduction of such a test in the near future.

### Meeting with Ortho on 23 August 1989

Ortho organised a meeting in London with representatives from both the English and Scottish blood services to look at the preliminary UKBTS data.<sup>746</sup> In advance of this meeting, Peter Savage of Ortho informed Dr Gunson that the US Food and Drug Administration (“FDA”) was expected to license the Chiron/Ortho test early in the first quarter of 1990, and that once the licence was granted “US Blood Banks will adopt the test immediately.”<sup>747</sup> At the meeting, and on top of this implied invitation to keep step with the US, Ortho sought to apply commercial pressure to secure an early commitment from the UK to order the Ortho test, though since it was also clear that Abbott Laboratories Ltd might develop a rival test in late 1990 it might have been that the pressures were not all one-way.<sup>748</sup>

744 The letter was in relation to anti-HIV 1 and 2 as well as anti-HCV testing.

745 Letter from Dr Gunson to all RTC directors 18 August 1989 PRSE0002340. The reference to the budget shows that at this stage Dr Gunson anticipated that universal screening for Hepatitis C might well be introduced between 1 April 1990 and 31 March 1991, and probably earlier than later in that period.

746 Dr Gunson, Dr Barbara, Dr Contreras for the NBTS; Dr Mitchell and Dr Edward Follett (of the SNBTS Microbiology Reference Unit) for SNBTS. Letter from Dr Mitchell to Professor Cash 25 August 1989 p1 PRSE0000815

747 Letter from Peter Savage to Dr Gunson 11 August 1989 NHBT0000188\_023

748 Ortho indicated that this year’s price would apply for an early decision, but thereafter the price would increase. Letter from Dr Mitchell to Professor Cash 25 August 1989 p3 PRSE0000815



It was made clear to Ortho that no decision had been made, that it was subject to the advice of the ACVSB, and that any recommendation from the ACVSB would go to ministers for a final decision. No decision was possible before the next meeting of ACVSB on 17 October 1989. If the test were to be introduced, then “*the UK would move in unity*”.<sup>749</sup>

### Press coverage in August 1989

On 24 August 1989, *The Guardian* ran a headline, “*Dilemma on virus blood test*”, over an article suggesting that health ministers would need to decide between introducing anti-HCV screening, “*which could seriously deplete the already falling number of blood donors*” or continuing to “*risk the safety of the national blood supply*”.<sup>750</sup> An internal Department of Health minute from Dr David Kennedy to Dr Rejman on 24 August 1989 about *The Guardian* article that day, noted that the Chiron/Ortho test was under evaluation by the BTS and PHLS, expressed some concern that it was currently a monopoly supply situation, and stated that another test, Fujiribo, was on the horizon.<sup>751</sup>

On 26 August 1989, *The Lancet* carried two letters on the topic of “*Screening for Hepatitis C Virus Antibody*”. The first, from Dr Contreras and Dr Barbara, acknowledged the Chiron/Ortho test to be a welcome advance, but argued that “*in the context of donor screening, precipitate action should be avoided.*” They stated that of the blood donations they had tested on behalf of the NBTS, 0.5-1% had been found to be repeatedly reactive, the equivalent of 12,500 to 25,000 donors per year. They warned that contacting and counselling affected donors would be “*an enormous and costly undertaking*”, that using an assay test that took three hours would be logistically difficult, and that a confirmatory assay was still required. The second letter was from Professor Cash and colleagues at the SNBTS. They also warned that the absence of a confirmatory test would cause serious problems for blood transfusion services, “*which are likely to bear the brunt of sensitive donor counselling.*”<sup>752</sup>

749 At the meeting the figures from the trial conducted at the North London Blood Transfusion Service, and from the testing conducted on SNBTS samples were given by Dr Barbara and Dr Mitchell, respectively. This indicated that Hepatitis C was present in the order of 1:150 to 1:200 blood donors. Letter from Dr Mitchell to Professor Cash 25 August 1989 p2 PRSE0000815

750 The *Guardian Dilemma on virus blood test* 24 August 1989 p1 NHBT0000014\_060. A second article in *The Guardian* on the same day suggested that the most immediate concern facing the Department of Health was how to set up a mechanism and find the staff to tell donors the implications of carrying Hepatitis C antibodies. The article quoted Dr Contreras as saying “*The resource implications are enormous.*” The *Guardian Hepatitis test ‘may deter blood donors’* 24 August 1989 p2 NHBT0000014\_060. Further press coverage followed the next day. The *Independent Hepatitis blood test may hit transfusions* 25 August 1989, The *Guardian Call for action on blood checks, Trouble in the blood stream* 25 August 1989, The *Standard Hepatitis dangers ‘minimal’* 25 August 1989 and The *Times Hepatitis test to be considered* 25 August 1989 NHBT0000061\_042

751 Memo from Dr Kennedy to Dr Rejman 24 August 1989 DHSC0003583\_090

752 Letters to the Editor Contreras and Barbara, Cash et al *Screening for Hepatitis C Virus Antibody* The *Lancet* 26 August 1989 NHBT0083819. They followed two articles on the same topic in the 5 August 1989 edition: *Will the Real Hepatitis C Stand Up* and Esteban et al *Hepatitis C Virus Antibodies Among Risk Groups in Spain* The *Lancet* 5 August 1989 NHBT0000072\_026

## Rome Symposium 14-15 September 1989

The First International Meeting on the Hepatitis C Virus was held in Rome on 14 and 15 September 1989. Representatives from Austria, Belgium, Denmark, Germany, Finland, France, Italy, the Netherlands, Switzerland, Yugoslavia, the UK and the US presented the findings of their preliminary investigations into the Chiron/Ortho anti-HCV test. Dr Mitchell and Dr Gunson both attended. Dr Mitchell reported back to the ACTTD that *“The Chiron test is now being used in a large number of Blood Transfusion Laboratories throughout the World and one is struck by the rapidity of this introduction.”*<sup>753</sup> Dr Gunson recounted that although the studies presented were small scale due to the short time available, they had consistently shown that anti-HCV positivity indicated that a patient was suffering from non-A non-B Hepatitis, and that the test was indeed detecting a viral marker associated with NANBH. The findings also included that, in general, 70-80% of patients suffering from treated (or severe) haemophilia were anti-HCV positive. Several countries had tested blood donations for anti-HCV. Its prevalence was usually in the 0.5-1% range, save for in Italy where the level of NANBH was known to be higher.<sup>754</sup> A Spanish study had shown that approximately 60% of recipients of anti-HCV positive donor blood would go on to develop NANBH.<sup>755</sup>

## Department of Health discussions in October 1989

Dr Gunson wrote to Graham Hart, then director of operations of the NHS Management Board in the Department of Health,<sup>756</sup> on 2 October 1989, outlining the development of the Chiron/Ortho test and noted that:

*“There is no doubt that this test is detecting a virus which causes transfusion transmitted NANBH. With respect to English blood donors we have tested, retrospectively 9000 donor samples from three regions and found on average, a positive rate of 0.77%. Unfortunately, it is not known whether all these positives are truly positive since a confirmatory test is not yet available. This is being worked on at present by Chiron. Currently the test is not licensed by FDA.*

*I have asked the DH for finance to carry out pilot trials in three further RTCs (Brentwood, Birmingham and Sheffield) to determine how this test fits in with working practices.*

*The data concerning the test and its introduction will be presented to the DH Advisory Committee on the Virological Safety of Blood which next meets on*

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753 First International Meeting of Hepatitis C Virus 2 October 1989 p1 NHBT0000188\_059

754 Report on the Meeting in Rome to Discuss Chiron Testing 10 October 1989 p3 DHSC0003557\_053

755 Report on the Meeting in Rome to Discuss Chiron Testing 10 October 1989 p4 DHSC0003557\_053  
This version of Dr Gunson’s report was approved by the ACTTD for submission to the ACVSB.  
Minutes of ACTTD meeting 9 October 1989 pp3-4 NHBT0000043\_034

756 Written Statement of Sir Graham Hart p5 WITN7112001

*6th November 1989.<sup>757</sup> I think that a decision will be made to introduce routine screening during 1990.”<sup>758</sup>*

He gave an estimate of £5,620,000 for the cost of introducing routine screening nationally, including the test kits, staffing costs, counselling and follow-up of donors, and replacing lost donors. A handwritten note from Graham Hart recorded that this could add substantially to costs in 1990/91 and “*certainly in 91/92*” and sought further advice internally within the Department.<sup>759</sup>

On 3 October 1989, John Canavan wrote to the Department of Health Finance Division about a request from Dr Gunson of the NBTS for £25,000 to fund field trials in RTCs to assess the operational implications of using the Chiron/Ortho test for routine blood donor screening. He explained that recent pilot studies in the NBTS and elsewhere seemed to have confirmed the effectiveness of the Chiron/Ortho test. He noted that the ACVSB at its next meeting could well recommend the introduction of routine screening. He supported the request for funds, writing that:

*“You will appreciate that viral contamination through blood is a sensitive issue, particularly now that the HIV litigation is getting underway. The press has already run scare stories about HCV and commented on the need to adopt the new test as soon as possible. Clearly we need to keep up the momentum [sic] in evaluating the test by getting the field trial underway as soon as possible. I understand that Ortho have given Dr Gunson first refusal on a batch of tests and may make mischief if a decision is delayed.”<sup>760</sup>*

On 9 October 1989, Dr Metters, the Deputy Chief Medical Officer, wrote to Graham Hart regarding Dr Gunson’s letter of 2 October. He said that at their July meeting the ACVSB had concluded that there was insufficient data available on the test’s performance. The ACVSB had been concerned that the Chiron/Ortho test could not be independently validated “*and as a result we have no idea of the false positive or negative rate*”. He added that problems with specificity could deter the ACVSB from recommending its general introduction. He noted that no country had yet put the test into routine use, and that it was unlikely to be granted an FDA licence until spring 1990 “*at the earliest*”. His view was that the ACVSB might await the FDA’s decision before making a recommendation for the UK:

*“The tone of Harold Gunson’s letter suggests that he is convinced that Chiron will eventually be introduced. However, my impression from the last meeting was that other members were much more sceptical, particularly on validation. Dr Gunson is, however, absolutely right to draw attention to the financial implications for*

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757 The anticipated date of 17 October 1989 which had been referred to in earlier discussions and correspondence had been put back by some three weeks.

758 Letter from Dr Gunson to Graham Hart 2 October 1989 p2 NHBT0000188\_056

759 Letter from Dr Gunson to Graham Hart 2 October 1989 p1 NHBT0000188\_056

760 Memo from John Canavan to Jane Wheeler 3 October 1989 NHBT0000188\_062. In oral evidence to the Inquiry, John Canavan stated that he was trying to build a justification for spending the money. John Canavan Transcript 22 September 2022 pp46-47 INQY1000244

*BTCs [blood transfusion centres] ... The Committee are well aware of the cost implications and the need for a uniform policy for all UK BTCs. However I do not think it is a foregone conclusion that ACVSB will recommend its introduction at their November meeting. They may well opt 'to wait FDA's consideration'.*<sup>761</sup>

## ACTTD meeting 9 October 1989

Meanwhile, the ACTTD met on 9 October 1989.<sup>762</sup> The ACTTD's role was to brief the ACVSB, which was tasked with making a formal recommendation to the Department of Health, where a decision whether to introduce anti-HCV screening would be taken.<sup>763</sup>

The ACTTD decided that an updated version of Dr Gunson's report on the Rome symposium should be submitted. Professor Cash raised the issue of counselling and follow-up referrals for donors who screened positive, as well as "*the need for flow charts*"; Dr Gunson observed that these matters would form part of the policy decisions to be taken if the Department of Health accepted the recommendation of the Committee.<sup>764</sup>

Dr Gunson's revised *Report on the Meeting in Rome to Discuss Chiron Testing* was duly submitted to the ACVSB. At the end of the report, Dr Gunson drew a number of conclusions from the information presented at the symposium, including that "*Evidence presented suggested that routine anti-HCV tests on blood donations would reduce the incidence of transfusion transmitted NANBH*".<sup>765</sup> He noted that Chiron had announced that it was working on a recombinant immunoblot assay ("RIBA") confirmatory test, but that it was not yet available.<sup>766</sup> The recommendation to the ACVSB was:

*"Routine screening of blood donations for anti-HCV should be introduced when practical, since there is, even from the early international studies, the probability that the incidence of transfusion transmitted NANBH will be reduced.*

*The Committee is asked to approve the routine testing of blood donations for anti-HCV in principle and request the National Directors in England and Scotland*

761 Memo from Dr Metters to Graham Hart 9 October 1989 NHBT0000188\_074. Dr Pickles gave evidence that it was the preference, but not a formal requirement, that the test be licensed in the US by the FDA before being adopted for use in the UK. Dr Hilary Pickles Transcript 12 May 2022 pp185-186 INQY1000205

762 Minutes of UK ACTTD meeting 9 October 1989 NHBT0000043\_034. The meeting was chaired by Dr Gunson with Professor Cash and Drs Contreras, Follett, Mitchell and Mortimer in attendance.

763 Asked about this decision-making process, Dr Contreras commented on "*the lack of speed*" with which decisions were taken in this period. Professor Dame Marcela Contreras Transcript 3 December 2021 p88 INQY1000166

764 Minutes of UK ACTTD meeting 9 October 1989 p3 NHBT0000043\_034

765 Report on the Meeting in Rome to Discuss Chiron Testing by Dr Gunson 10 October 1989 p5 DHSC0003557\_053

766 According to Dr William Wagstaff: "*The original recombinant immunoassay, RIBA-1, was a test that involved a search for antibodies against the same two recombinant antigens used in the initial ELISA screen. Thus, it can only be described as supplementary rather than confirmatory. RIBA-1 was supplanted by RIBA-2 which contained a further two recombinant antigens, i.e., a total of four. Strictly speaking this was still a supplementary test rather than confirmatory but proved to be much more reliable than RIBA-1 and was accepted for regular use in the UK in April 1991.*" Written Statement of Dr William Wagstaff paras 598-599 WITN6988001

*to arrange for the simultaneous introduction of the tests at an appropriate time when a policy for counselling and management of the seropositive donors has been defined.”*<sup>767</sup>

Dr Gunson’s report added that every effort must be made to ensure that a confirmatory test was available in the UK at the time routine donor screening was introduced. It can be seen that the recommendation was dependent on further steps and no specific timescale was mentioned. The report also suggested that the routine use of the test for blood donations in the UK should not commence before an FDA licensing procedure was effected.<sup>768</sup>

The annual costs of routine anti-HCV tests on blood donations in England and Wales were estimated to amount to (at least) £5,620,000.<sup>769</sup>

### **Further views being put to the ACVSB and Department of Health in October 1989**

On 16 October 1989, Dr Lane wrote to Dr Rejman at the Department of Health under the subject line, *“Immune Markers for Hepatitis C Virus (non-A non-B)”*, raising concerns in advance of the forthcoming ACVSB meeting. His view was that the presence of antibody for Hepatitis C was not necessarily a marker of infectivity and that the implications of testing for fractionation and segregation of plasma stocks required further discussion.<sup>770</sup>

On 17 October 1989, Dr Mortimer of PHLS also wrote to Dr Rejman, expressing a different view: *“As regards Hepatitis C virus antibody testing the case for screening is very strong and as soon as FDA approves screening by the Ortho test and/or Abbott test in USA I think we should endeavour to screen universally here. If we do not act fairly quickly and cases of post transfusion hepatitis attributable to HCV arise I think we shall be in a weak position.”*<sup>771</sup>

Dr Edward Tuddenham also wrote in support of testing: *“I would strongly support moves to extensively evaluate the test based on detection of antibody to polypeptide synthesised by recombinant yeast clones of this virus (HCV). It may well be that screening donor blood by*

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767 Report on the Meeting in Rome to Discuss Chiron Testing by Dr Gunson 10 October 1989 p6 DHSC0003557\_053

768 Report on the Meeting in Rome to Discuss Chiron Testing by Dr Gunson 10 October 1989 p7 DHSC0003557\_053. His views were succinctly and accurately summarised by Dr Contreras to a meeting of the Eastern Division of Consultants in Blood Transfusion as being that the UK should start testing only when there was: (a) FDA licensing, (b) confirmatory testing available, and (c) provision for counselling. The minutes record the expectation that the UK would commence testing in around June/July 1990. Minutes of Eastern Division of Consultants in Blood Transfusion meeting 18 October 1989 p6 NHBT0017553\_001. In evidence, Dr Contreras said that arranging provision for counselling was an issue of cost and manpower. Professor Dame Marcela Contreras Transcript 3 December 2021 pp90-91 INQY1000166

769 Report on the Meeting in Rome to Discuss Chiron Testing by Dr Gunson 10 October 1989 p12 DHSC0003557\_053

770 Letter from Dr Lane to Dr Rejman 16 October 1989 NHBT0000041\_081. It is surprising that he expressed this view given the apparent scientific consensus which Dr Gunson and the ACTTD were reporting to an opposite effect, which Dr Mortimer and Professor Cash appeared to endorse.

771 Letter from Dr Mortimer to Dr Rejman 17 October 1989 DHSC0003557\_041



*such an assay could reduce the transmission rate of non A, non B hepatitis in single donor products and in some pooled plasma derivatives.”<sup>772</sup>*

Dr Lane, Dr Mortimer and Dr Tuddenham were members of the ACVSB at this time.<sup>773</sup>

### **ACVSB meeting 6 November 1989**

The ACVSB held its fourth meeting on 6 November 1989.<sup>774</sup> Dr Metters chaired, and his brief circulated in advance of the meeting noted in relation to non-A non-B Hepatitis, “*The main issue for the Committee is whether the time is right to make a decision about adopting the Chiron test*”.<sup>775</sup>

Dr Gunson presented his report and explained that ACTTD’s conclusion was that:

*“the test will detect a viral marker to NANB, a positive test may mean blood is infected (but not always), and that routine testing for anti-HCV will reduce NANB, but estimates of the extent of the reduction range from 20%-60%. The problems that were identified were the lack of a confirmatory test, and a question mark hanging over the status of the ALT and anti-HBc testing. The recommendations were that routine screening should be introduced only after a confirmatory test becomes available, after the FDA have approved the test and urgent pilot studies have been carried out in this country.”<sup>776</sup>*

During the discussion that followed, concerns were expressed about the suitability of the Chiron/Ortho test for testing pooled UK plasma. Dr Richard Tedder suggested that better tests could follow in future. Dr Metters recognised the possibility that a prolonged delay in introducing screening could result in litigation, but nonetheless saw a need for “*more facts and figures*”. There was also a discussion about prevalence; Dr Gunson thought that 1:200 patients could go on to develop chronic hepatitis, while others felt that taking into account asymptomatic seroconversion the figure could be higher. The “*feeling*” of the Committee was that:

*“the test represented a major step forward, but that the Committee need to know a great deal more about it, and acknowledged the need for a confirmatory test. It was agreed that while the UK would not want to go on in advance of an FDA decision, it could prove difficult if the FDA do not decide in favour of the test. Nevertheless, it was felt that if the UK do put the test into general use RTCs will need to have had experience with it, and therefore pilot studies should go on in Birmingham, Sheffield and Brentwood, to show the feasibility of adding this test to routine practice.”<sup>777</sup>*

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772 Letter from Dr Tuddenham to John Canavan 17 October 1989 NHBT0000041\_080

773 Though Dr Tuddenham was not present at the ACVSB meeting on 6 November 1989.

774 Minutes of ACVSB meeting 6 November 1989 NHBT0005043

775 Chairman’s brief of ACVSB meeting 6 November 1989 p2 DHSC0002495\_064

776 Minutes of ACVSB meeting 6 November 1989 p4 NHBT0005043

777 Minutes of ACVSB meeting 6 November 1989 pp4-5 NHBT0005043

Dr Metters stated that the Procurement Department had made available the £25,000 funding requested to conduct a pilot study.<sup>778</sup>

The minutes recorded that the ACVSB would support the general introduction of the Chiron test “if the FDA approves it, and the pilot shows it to be feasible and non-problematic.”<sup>779</sup> It was felt that the Committee should therefore be developing an economic case for the Department to fund the test’s routine use.<sup>780</sup>

Following the meeting, Dr Metters wrote to Dr Rejman:

*“Following yesterday’s meeting of ACVSB the Committee’s advice to the Department is clear, but what will be far more difficult to demonstrate is the practical benefits from the introduction of the Chiron test.*

*This was discussed by the Committee and you heard their doubts. Nevertheless, if we are to convince Ministers that the test represents ‘good value’ we need to produce data about the number of cases of hepatitis that might be prevented, and not just rely on the argument that it is just another screening test<sup>781</sup> that will improve the safety of blood and blood products.”<sup>782</sup>*

### Pilot study and cost considerations

Dr Gunson followed up on the £25,000 grant of funding by submitting a draft protocol for a pilot study in Birmingham, Sheffield and Brentwood to the NHS Procurement Directorate on 8 November 1989.<sup>783</sup> His proposals were agreed and the study took place over a two-week period commencing early December 1989.<sup>784</sup> Dr Gunson presented the preliminary results at a meeting on 18 December 1989 between the NBTS and representatives of Ortho.<sup>785</sup> At Sheffield, 0.18% of samples repeatedly tested positive, at Birmingham 0.24% samples, and at Brentwood 0.85%. There were higher positivity rates in samples taken from patients who

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778 Minutes of ACVSB meeting 6 November 1989 p5 NHBT0005043

779 Minutes of ACVSB meeting 6 November 1989 p5 NHBT0005043. These were two of the three preconditions which Dr Gunson had identified. The third, a need for confirmatory testing, did not appear in this part of the minutes.

780 Minutes of ACVSB meeting 6 November 1989 p5 NHBT0005043

781 This is a somewhat unfortunate phrase, given that blood was routinely screened for syphilis, Hepatitis B, and HIV. None of those were easily dismissed as “just another screening test”, as if non-essential.

782 Memo from Dr Metters to Dr Rejman 7 November 1989 WITN7115007. On the same day, Dr Metters also wrote to Dr Rejman that Dr Gunson was being contacted by the media regarding the prospects for introducing Hepatitis C testing, and suggested that the Press Office be given an updated brief. Memo from Dr Metters to Dr Rejman 7 November 1989 NHBT0000061\_072

783 Letter from Dr Gunson to Dr Kennedy 8 November 1989 NHBT0000014\_082. Draft protocol of pilot study to assess the introduction of routine anti-HCV tests in RTCs 8 November 1989 NHBT0000188\_103

784 Letter from J Macleod to Dr Gunson 6 December 1989 NHBT0015984. Written Statement of Dr Harold Gunson in *A and Others v National Blood Authority* p32 NHBT0000026\_009

785 Minutes of NBTS HQ meeting 18 December 1989 NHBT0000188\_136. The attendees were Dr Gunson, Dr Mitchell of the West of Scotland Blood Transfusion Service, Dr James of Sheffield Blood Transfusion Service, John Francis of the SNBTS, Peter Savage and Allan Follett from Ortho, Roy Davis from Johnson & Johnson, the parent company, and Mark Fuller of the NHS Procurement Directorate. The Ortho and Johnson & Johnson attendees joined the meeting part way through following an initial discussion of the pilot study results.

were HIV positive, had haemophilia, or had liver pathologies. Taken in conjunction with the results from the earlier three-centre NBTS study, Dr Gunson concluded that there may be an incidence of anti-HCV positivity in the “*healthy*” population of 1 in 200, meaning that 0.5% of blood donations could be positive and possibly transmit an infective agent. This would imply 6,250 infections from the 1.25 million current blood donors with each giving 2 donations a year and half of the recipients dying from the original condition that required a transfusion. It was assumed that 1 in 10 of those infected who had been previously well might get liver disease within ten years.<sup>786</sup> A further implication, however, is that if there were 6,250 donors who were carrying the infection, then only 0.5% of the total donor base would be lost to the donation system if all were to be rejected as donors in future.

A note of the meeting records that “*No publication of the survey result is advocated until a decision on future policy has been made and published.*” The implications of screening were “*manifold, and difficult to resolve at this stage*”, including a lack of confirmatory testing, counselling policy, available treatment and clinical evidence of predictive outcomes. However, a confirmatory RIBA test was under development in the US; and it was anticipated that confirmatory testing would be carried out at PHLS. Dr Virge James of the Sheffield RTC confirmed that there were no technical or logistical difficulties involved in using the test. It was acknowledged that France, Japan and Canada had already elected to introduce screening using the Chiron/Ortho test. Ortho’s proposed cost price of between £2.00 and £2.40 per test was, however, a “*sticking point*”. Mark Fuller, who took the note, commented that “*The meeting conveyed the concern of the BTS that a decision should be made as soon as possible ... Obviously in the forefront of minds are liability implications.*” However, he felt that “*a monopoly-based supply decision would be precipitous at this stage.*”<sup>787</sup>

Of the two preconditions which the ACVSB had set itself on 6 November – that “*ACVSB would support the general introduction of the Chiron test if the FDA approves it and the pilot shows it to be feasible and non-problematic*” – it follows that the second had been met.<sup>788</sup>

On 4 January 1990, Dr Gunson presented the results of the pilot study to a meeting of the National Management Committee of the NBTS and undertook to prepare a more comprehensive report for the ACVSB. He also informed the Committee that an alternative test marketed by Abbott was now available for evaluation. He advised that the ACVSB did not see the absence of a confirmatory test as a barrier to the introduction of routine screening, but that it would insist that any routine test be licensed by the FDA.<sup>789</sup>

Meanwhile, in November 1989, the FDA had granted a permit for the Chiron/Ortho test to be exported for diagnostic use as well as research.<sup>790</sup>

786 Minutes of NBTS HQ meeting 18 December 1989 pp1-4 NHBT0000188\_136

787 Minutes of NBTS HQ meeting 18 December 1989 p3, pp5-6, p7, p9 NHBT0000188\_136

788 Of the three preconditions which Dr Gunson had suggested, the third (confirmatory testing) was now clearly on the way. Minutes of ACVSB meeting 6 November 1989 pp4-5 NHBT0005043

789 Minutes of NBTS Management Committee National Directorate meeting 4 January 1990 pp4-5 NHBT0071870\_002. The attendees were Dr Gunson, Dr Fereydoun Ala, Dr Contreras, Dr Ian Fraser, Dr Jean Harrison, Dr Douglas Lee, Dr Roger Moore, Dr Wagstaff and Peter Cosgrove.

790 Letter from Peter Savage to Professor Cash 27 November 1989 NHBT0000188\_123

## ACVSB meeting 17 January 1990

The ACVSB held its fifth meeting on 17 January 1990.

Dr Gunson presented a paper in which he set out the results of the pilot study and commented that all participants had found the test straightforward and easy to perform.<sup>791</sup> There were aspects that would have to be discussed with Ortho, such as the number of below-threshold reactive samples.<sup>792</sup>

The chair then invited the Committee “*to address the question of whether the time has now come for the introduction of routine Hep C testing.*”<sup>793</sup> Professor Arie Zuckerman spoke to a document he had submitted, in which he recommended that the UK should await the decision on licensing by the FDA, expected at the end of March 1990, before introducing screening. He also suggested that the Abbott test, then under development, should be evaluated. However, he warned that despite “*very high*” projected initial costs, “*considering the overall morbidity of chronic non-A, non-B hepatitis (including apparently autoimmune liver disease and hepatocellular carcinoma), and litigation which would be indefensible, the introduction of screening could not be delayed much beyond FDA approval.*”<sup>794</sup> In the meeting, Professor Zuckerman said that up to 5,000 donors could be excluded from donating based on estimates of using routine testing, but that up to 50% could be false positives, and advocated keeping an open mind about other tests which should become available within the next 12 months.<sup>795</sup>

Dr Hilary Pickles, a Principal Medical Officer in the Department of Health, presented a paper on the *Cost-Benefit of Hepatitis C Screening of Blood Donors in the UK.*<sup>796</sup> Total costs were estimated at £7.72m plus unquantifiable additional administrative costs. However, the benefits were not quantified. It was thought that perhaps 1% of recipients of infected blood would develop acute hepatitis, of whom perhaps 10% would develop chronic hepatitis, although it is unclear where these figures were taken from. The risk of subsequent litigation was noted to be potentially “*substantial if other nations institute screening.*”<sup>797</sup>

Following discussions, Dr Metters summed up that the “*general consensus of the Committee*” was that routine testing should not be introduced in advance of the FDA decision, and that “*scientifically, not enough is known yet, but there is agreement that the test does detect some people who will transmit.*” It was agreed that costs should be looked at now, with regions

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791 Pilot Trial of Anti-HCV Tests on Blood Donations by Dr Gunson 10 January 1990 NHBT0000061\_095

792 Minutes of ACVSB meeting 17 January 1990 p3 PRSE0001477

793 Minutes of ACVSB meeting 17 January 1990 p3 PRSE0001477. This was, in effect, the second time of asking: it had been the central topic at the ACVSB meeting two months earlier on 9 November 1989.

794 Letter from Professor Zuckerman to Dr Rejman p2 NHBT0000041\_088

795 Minutes of ACVSB meeting 17 January 1990 pp3-4 PRSE0001477

796 Cost-Benefit of Hepatitis C Screening of Blood Donors in the UK January 1990 NHBT0000189\_001. The Committee were also provided with a letter from Dr Elwyn Elias to Dr Rejman from 2 January 1990, providing a negative view on the introduction of donor screening. Letter from Dr Elwyn Elias to Dr Rejman 2 January 1990 NHBT0000189\_003

797 Cost-Benefit of Hepatitis C Screening of Blood Donors in the UK January 1990 pp2-3 NHBT0000189\_001

being called upon to consider the financial implications (the decision having apparently been taken, or so the chair explained, that funding would have to be found from “*the existing health vote allocation*”). The Committee “*could give no further scientific advice at this point, but would discuss the matter further at the next meeting (April) which would be after the International Hepatitis Meeting in Houston*”. In the meantime further work should be done to calculate working estimates of the number of possible preventions.<sup>798</sup>

Dr Mitchell recorded highlights from the meeting, including “*Agreed not to introduce test in advance of FDA approval **but very compelling reasons to implement quickly following U.S. decision.***”<sup>799</sup> This was entirely consistent with the view taken by ACVSB on 6 November 1989.

However, the minutes show that Dr Mortimer had argued in favour of an earlier introduction: “*Dr Mortimer felt that as the perceived risk is higher than that of HIV, we would be inconsistent in our screening procedure if we did not introduce routine testing. If we began routine use of this test we should soon have a better test to move onto.*”<sup>800</sup>

The ACVSB agreed that “*in view of media interest*” a submission to ministers should set out the present position and its views.<sup>801</sup>

On 2 February 1990, Dr Pickles followed up on the meeting by writing to Dr Rejman and John Canavan, emphasising that “*we must not delay in seeking help elsewhere in the department in refining our assessment of the cost-benefit of hepatitis C screening.*”<sup>802</sup>

A submission was sent for the attention of Baroness Gloria Hooper, Parliamentary Under-Secretary of State for Health in the House of Lords, on 15 February 1990, noting that the ACVSB had decided that there was still insufficient scientific information about the Ortho test to advise its routine introduction. Ministers would, the note said, be kept informed of any further advice from the ACVSB, immediately after its April meeting.<sup>803</sup>

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798 Minutes of ACVSB meeting 17 January 1990 pp4-5 PRSE0001477

799 Emphasis added. Note of ACVSB meeting 17 January 1990 p1 SBTS0000501\_238. As will be apparent from this chapter, those “*very compelling reasons*” did not in fact lead the ACVSB or the Department of Health or any others involved to “*implement quickly*” following the FDA’s approval.

800 Minutes of ACVSB meeting 17 January 1990 p4 PRSE0001477. On the issue of handling donors, Dr Mitchell thought it was possible to deal with the donors who proved positive to the test without causing undue alarm.

801 Minutes of ACVSB meeting 17 January 1990 p5 PRSE0001477

802 Memo from Dr Pickles to Dr Rejman and John Canavan 2 February 1990 DHSC0002496\_076

803 Memo from Pam Reenay to Dr Metters and Private Secretary to the Parliamentary Under-Secretary of State in the Lords 15 February 1990 NHBT0000189\_055. Handwritten on the submission is Dr Metters’ comment: “*The clear advice from ACVSB is that, as yet, there is not enough scientific data about the test marketed by Ortho for the Committee to recommend that it be introduced.*” In view of the summary of the 6 November meeting, set out above, this comment by Dr Metters is surprising. The minutes of the January meeting had included the words: “*scientifically, not enough is known yet, but there is agreement that the test does detect some people who will transmit*”. However, the handwritten note was incomplete – it neither contained the qualification nor did it record the sense that the Committee thought in January that there were “*very compelling*” reasons to introduce the test once the FDA had approved it, nor its earlier decisions as set out in the text. In short, it was incomplete. Minutes of ACVSB meeting 17 January 1990 p5 PRSE0001477, Note of ACVSB meeting 17 January 1990 p1 SBTS0000501\_238



At the time that the responsible minister was being informed that there was insufficient information to enable a decision to be taken, Australia was introducing routine screening, France was about to introduce it, and it had been in place in Japan since November.<sup>804</sup>

Dr Gunson reported back to the ACTTD at its next meeting that the ACVSB had deferred the decision to introduce routine anti-HCV testing, and that it was hoped that they would have the information needed to make the decision at the next ACVSB meeting at the end of April 1990.<sup>805</sup>

### Dr Frank Boulton's view

On 8 February 1990, Ortho organised a second Hepatitis C Symposium in London.<sup>806</sup> Dr Frank Boulton of the Edinburgh and South East Scotland Blood Transfusion Service took a note of the talks given, which he sent to Professor Cash at the SNBTS by letter of 21 February 1990. His note shows that at the symposium Dr Barbara gave a talk on *HCV and the Blood Transfusion Service* which suggested that the predictive value of anti-HCV screening would be low in low prevalence populations.<sup>807</sup> Nonetheless, Dr Boulton urged Professor Cash to support its introduction:

*“Could I just add that in spite of obvious difficulties with the current Ortho Elisa assay (susceptibility [sic] to ‘stickiness’, unreliability [sic] of predictive [sic] value with heat treated samples, etc) I have developed a very strong feeling that the screening of donors for HCV antibodies should be introduced at the earliest possible [sic] opportunity. This is not because of the ‘science’, but because there appears to be little doubt that people have contracted HCV as a result of transfusions which they would not have received had those transfusions been screened for HCV antibody. Furthermore there are apparently five known cases of HCC due to PTH [post-transfusion hepatitis]. The reason, therefore, from my proposing this view [sic] is actually one based on future litigation. I am pretty convinced that the NBTS and SNBTS will find legal action taken against them in about 10 years’ time from persons who have sustained post transfusion hepatitis as a result of receiving HCV antibody containing blood which was presumably infectious for HCV at the time.”<sup>808</sup>*

In his written statement to this Inquiry, Dr Boulton explained that “‘litigation’ should be viewed as a sort of surrogacy for ‘responsible practices’”, which would involve balancing the need to secure clinical supplies of donor blood with patient welfare and the minimisation

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804 *A and Others v National Blood Authority* Judgment 26 March 2001 para 143 PRSE0003333

805 Minutes of ACTTD meeting 16 March 1990 p2 NHBT0000043\_047. At the meeting, Dr Mitchell presented a draft flow chart for the management of donors testing anti-HCV positive.

806 The abstracts from the talks delivered at the symposium can be found in: Report on Ortho HCV Symposium 8 February 1990 PRSE0004275

807 Report of HCV Symposium organised by Ortho 8 February 1990 pp1-2 PRSE0004402

808 Letter from Dr Boulton to Professor Cash 21 February 1990 PRSE0001562

of risk, even using an imperfect testing method.<sup>809</sup> His view at the time of providing his statement was that *“the UKBTSs should have introduced HCV screening in 1990 using the then-available technology, and should have been fully funded centrally to cover the extra expenditure involved in donor counselling and the recruitment of new donors.”*<sup>810</sup> Dr Boulton told the Inquiry that he felt there was an ethical need to introduce Hepatitis C screening at the earliest opportunity, and that *“somewhat to our shame the UK was among the latest countries in Europe to actually introduce the testing.”*<sup>811</sup>

### ACVSB meeting 24 April 1990

The sixth meeting of the ACVSB took place on 24 April 1990. Dr Metters reported to the meeting that France, Belgium and Luxembourg had all commenced mandatory screening, while Italy had introduced optional screening.<sup>812</sup> A follow-up note of the meeting which Dr Robert Perry sent to Professor Cash additionally noted that Hepatitis C testing was in place in Finland and Australia.<sup>813</sup> Giving evidence to the Inquiry, Dr Rejman said that the virologists at the meeting would already have been aware of the international picture, and so Dr Metters was not imparting new information but rather mentioning a known fact to bear in mind.<sup>814</sup>

Papers presented at the meeting included a report on the 8 February 1990 Hepatitis C Symposium.<sup>815</sup> Dr Rejman presented the report’s conclusion: *“The overall impression was that the test was not sensitive or specific enough for reliable testing.”*<sup>816</sup> Dr Mortimer commented in relation to the symposium that he thought there had been an underlying feeling against screening because of the lack of confirmatory testing, but this would become available within a reasonable time and that the *“routine screening of blood donors could not be delayed for a long time”*. Professor Zuckerman said the non-specificity and sensitivity of the test had been the main talking points.<sup>817</sup>

Dr Mitchell reported on the Abbott Symposium and presented US guidelines on the implementation of anti-HCV testing.<sup>818</sup> He confirmed that FDA approval had not yet been given, but the American Association of Blood Banks had directed that testing should be introduced as soon as that happened.<sup>819</sup>

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809 Written Statement of Dr Frank Boulton paras 382-384 WITN3456002

810 Written Statement of Dr Frank Boulton para 402 WITN3456002

811 Dr Frank Boulton Transcript 4 February 2022 pp148-150 INQY1000181

812 Minutes of ACVSB meeting 24 April 1990 p3 NHBT0000072\_098

813 Letter from Dr Perry to Professor Cash 2 May 1990 enclosing notes of ACVSB meeting 30 April 1990 p3 PRSE0004633

814 Dr Andrzej Rejman Transcript 11 May 2022 pp122-123 INQY1000204

815 Report on Ortho HCV Symposium 8 February 1990 PRSE0004275

816 Minutes of ACVSB meeting 24 April 1990 p2 NHBT0000072\_098

817 Minutes of ACVSB meeting 24 April 1990 p2 NHBT0000072\_098

818 Guidelines for Planning the Implementation of Anti-HCV Testing of Blood and Components for Transfusion 8 February 1990 NHBT0000072\_070

819 Minutes of ACVSB meeting 24 April 1990 p2 NHBT0000072\_098

Professor Zuckerman presented a paper on US studies and commented that the RIBA test was not good enough to use routinely as a confirmatory test.<sup>820</sup> Professor Tedder presented a paper on the development of a novel PCR-based<sup>821</sup> assay that might in future provide another test.<sup>822</sup>

The Committee was also provided with an internal Department of Health economic analysis of the implications of introducing anti-HCV screening, which suggested more data was required to assess the value of benefits that could be achieved.<sup>823</sup>

The minutes record that during the discussion on anti-HCV testing, Dr Metters commented that the “*science seemed to have advanced little*” since the previous meeting, and that there were still questions as to whether the anti-HCV test was reliable and a useful step forward. Dr Gunson said that he found the US data about eliminating anti-HCV positive donors, in some series leading to a 50% reduction in post-transfusion non-A non-B Hepatitis, persuasive. He suggested that a further study be carried out by selective RTCs using both Ortho and Abbott tests, with confirmatory laboratory testing of repeatedly positive samples. Dr Mortimer considered that, “*the argument now was not whether we should test for hepatitis C but whether the tests were adequate*”, and he also supported a further pilot study. Other attendees raised concerns about the rate of false positives and the lack of FDA approval for the Ortho test.<sup>824</sup>

Dr Perry’s note of the meeting suggested that he and Dr Gunson had “*felt that there was sufficient data to justify testing now (based on U.S. data suggesting 50% reduction in PTH) but the majority and D.O.H. preferred more cautious approach.*”<sup>825</sup> Professor Cash gave evidence to the Penrose Inquiry that Dr Gunson and Dr Perry had argued that there was already sufficient data for the ACVSB to recommend to ministers the introduction of a first-generation Hepatitis C donation screening as soon as possible, but their views were rejected.<sup>826</sup> Dr Rejman’s recollection when giving evidence to the Inquiry was that there were too many downsides to the test, including the impact of false positive results for donors and lack of FDA approval, for the experts on the ACVSB to recommend its implementation.<sup>827</sup>

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820 Recombinant immunoblot assay test. Notes on anti-HCV testing by Professor Zuckerman, Minutes of ACVSB meeting 24 April 1990 p3 NHBT0000072\_098. He explained in the *A and Others v National Blood Authority* litigation that he meant that it was not genuinely a confirmatory test because it also tested for the antibody, rather than a comment on its unreliability as such. *A and Others v National Blood Authority* Judgment 26 March 2001 para 153 PRSE0003333

821 Polymerase chain reaction.

822 Detection of Hepatitis C Viral Sequences by “Nested” PCR Predicts Infectivity of Anti-C100 Positive Blood Donors 10 April 1990 HSOC0011581

823 Screening Blood Donations for Hepatitis C: Economic Appraisal: Note by Economic Advisers’ Office NHBT0000061\_127. Letter from Robert Anderson to John Canavan 20 April 1990 NHBT0000061\_126

824 Minutes of ACVSB meeting 24 April 1990 pp3-4 NHBT0000072\_098

825 Letter from Dr Perry to Professor Cash 2 May 1990 enclosing notes of ACVSB meeting 30 April 1990 p3 PRSE0004633

826 Written Statement of Professor John Cash to the Penrose Inquiry pp6-7 PRSE0002529. He added, “*I recall that Dr Gunson was distressed at this turn of events and repeatedly emphasised to me that the ACVSB was in the hands of DHSS officials and the academic virologists and that his role as DHSS adviser was being openly challenged.*”

827 Dr Andrzej Rejman Transcript 11 May 2022 p125 INQY1000204

Dr Metters summarised the views of the group, including that: there was inadequate scientific data to support the introduction of the Ortho test for routine screening; a confirmatory test was needed that could be used in RTCs and not just specialised laboratories; it would be reassuring if the FDA approved the test; there was a need to learn more about the donor panels and the significance of a positive reaction to the test; and a prospective study involving 25,000-50,000 donors would generate sufficient positives for confirmatory testing.<sup>828</sup> The outcome of the meeting therefore was not to approve the introduction of general screening, but to commence a further pilot study.

John Canavan followed up by drafting a short ministerial submission. He noted that screening of all donations had recently been introduced in France, Belgium, Luxembourg and Finland, and voluntary screening in Italy. However, FDA approval was still awaited and the ACVSB had “*reaffirmed its view that the introduction of routine screening would not yet be justified*”. He explained that a working party of the ACVSB was drawing up a protocol for the pilot study and there would be a request for funding, but until the size and nature of the study were defined, it would be difficult to estimate a cost.<sup>829</sup> He also wrote to the Scottish Home and Health Department notifying it of the decision to undertake a pilot testing study.<sup>830</sup>

John Canavan’s evidence to the Inquiry was that the reasons why other countries had introduced anti-HCV screening ahead of the UK were not considered at the time since the ACVSB knew of those developments but did not change its advice to wait.<sup>831</sup>

### **FDA approval 2 May 1990**

Only eight days later, after this inconclusive meeting looking for further studies, the FDA approved the Ortho anti-HCV ELISA test. Ortho publicised the decision on 4 May 1990, announcing that:

*“We are very pleased to inform you that the United States Food and Drug Administration, on Wednesday May 2, 1990, licensed the Ortho HCV ELISA Test System. Kits are now being shipped to U.S. blood centres and screening of the U.S. blood supply will commence immediately.*

*Ortho is also supplying HCV Test Kits to Europe, Japan, Canada and Australia for blood screening.*

*The routine availability of the Ortho HCV ELISA Test System marks a new era in the safety of blood transfusions as blood donation centres will now be able to identify the majority of blood that could potentially cause transfusion-associated hepatitis.*

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828 Minutes of ACVSB meeting 24 April 1990 p4 NHBT0000072\_098

829 Memo from John Canavan to Dr Metters and Elizabeth Baldock 1 May 1990 NHBT0000061\_130

830 Memo from John Canavan to Robert Panton 2 May 1990 ARCH0003310\_007. Robert Panton duly requested funding for the pilot study by letter on 18 June 1990. Memo from Robert Panton to Peter Hancock 18 June 1990 PRSE0000744

831 John Canavan Transcript 22 September 2022 pp61-62 INQY1000244

*We appreciate the many contributions of clinical investigators and collaborators around the world that enabled us to bring this important new test to market.”<sup>832</sup>*

The US blood banks commenced anti-HCV screening immediately following the FDA decision.<sup>833</sup>

On 11 May 1990, Dr Pickles sent a note to the Secretary of State’s office, Baroness Hooper’s private secretary and others in the Department of Health:

*“there remains the question of whether the NBTS should as an additional measure screen donations for hepatitis C to protect transfusion recipients. This is now being done in Japan, Belgium, Luxembourg, Finland and very recently in the USA. The Department’s advisory committee on the Virological Safety of Blood, under Dr Metters, have been considering the available evidence, in particular on the significance of a positive with this new test. The committee recommend further work on UK donors before a decision can be made.”<sup>834</sup>*

On 22 May 1990, Allan Follett of Ortho wrote a letter to customers stating:

*“We are now pleased to announce that the Ortho HCV Elisa Test System has been licensed by the US Food and Drug Administration and screening of the US blood supply has already started. In addition, many other countries including France, Japan, Spain, Finland, Canada, Italy and Australia are now using the new Ortho test for blood screening.*

*The routine availability of the Ortho HCV Elisa Test System and the Ortho Chiron RIBA HCV supplemental assay mark a new era in blood transfusion safety as the majority of blood units which cause post transfusion Hepatitis can now be identified.”<sup>835</sup>*

The FDA decision, though long expected, gave further weight to the argument for introducing screening in the UK. On 23 May 1990, the ACVSB working group on the further anti-HCV testing pilot, comprising Drs Gunson, Mitchell, Mortimer and Tedder, met Department of Health officials and decided that in light of the FDA decision, an extended study of RIBA and PCR techniques for confirmatory testing might no longer be appropriate.<sup>836</sup> The meeting was in effect proposing to abandon the one matter which the ACVSB’s last meeting had seen as standing in the way of immediate implementation of the test.

Dr Metters wrote a minute on 5 June 1990, suggesting that the next ACVSB meeting should be brought forward and solely devoted to the question of whether routine anti-HCV screening

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832 Announcement by Roy Davis, Managing Director of Ortho, 4 May 1990 NHBT0000189\_123

833 Associated Press *Blood Banks to Begin Using New Tests for Hepatitis C Virus* 4 May 1990 NHBT0000061\_134

834 Memo from Dr Pickles to Paul Ahearn and others 11 May 1990 p2 NHBT0000061\_137

835 Letter from Allan Follett to Ortho customers 22 May 1990 NHBT0016346

836 Memo from Dr Metters to Dr Rotblat, Dr John Purves, Dr Pickles, Dr Rejman and John Canavan 5 June 1990 DHSC0003973\_104



of blood donations should commence, as “*events are now moving fast.*”<sup>837</sup> He also wrote to Dr Gunson to the same effect.<sup>838</sup>

On 14 June 1990, John Canavan requested an updated cost-benefit analysis from the Economic Advisers’ Office, noting that “*our experts now seem to think advances in knowledge about the anti HCV test and the means of confirming the results make it very difficult to resist the introduction of screening. A number of countries have already done so.*”<sup>839</sup>

Also on 14 June 1990, Dr Metters asked Dr Rejman and John Canavan to provide “*the best available data on the sensitivity, specificity and predictive value of the Ortho and RIBA tests, preferably in tabular form.*”<sup>840</sup> Dr Rejman replied on 22 June 1990, having spoken to Dr Mortimer. He wrote that there was a lack of good data but that the Ortho and Abbott ELISA tests were not very specific when used prospectively in screening donors. His view was that screening of blood donations for Hepatitis C appeared to be of benefit to recipients but could pose major problems to donors given falsely positive results.<sup>841</sup> In evidence, he told the Inquiry that in giving this advice he bore in mind the low incidence of Hepatitis C in the UK population, that a large proportion of blood transfusion recipients die (from causes other than Hepatitis C) within a year or two of the transfusion, and that of recipients infected with Hepatitis C only a small proportion would experience chronic hepatitis, a smaller proportion cirrhosis, and a very small proportion liver cancer.<sup>842</sup>

### ACVSB meeting 2 July 1990

The next ACVSB meeting took place on 2 July 1990, earlier than had originally been planned. Dr Rejman introduced the discussion by setting out developments since the last ACVSB meeting: the FDA decision; the introduction of screening in the US (and that other countries were following); “*More studies had been carried out confirming that hepatitis C testing reduced infection*”; and RIBA was now available as a supplementary test. It was “*now felt that a study along the lines of those talked about in April was no longer viable and the meeting had therefore been brought forward so that a decision on the introduction of UK hepatitis C testing could be reached.*” The chair, Dr Metters, sounded a note of caution: he indicated that he was aware of the testing carried out in other countries, “*However,*

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837 Memo from Dr Metters to Dr Rotblat, Dr John Purves, Dr Pickles, Dr Rejman and John Canavan 5 June 1990 DHSC0003973\_104. The significant development was FDA approval. Since this had long been anticipated, it is difficult to see why matters were now moving fast. It might have been thought, for instance, that preparations should have been made for the introduction of universal screening forthwith upon FDA approval, given the earlier decisions of the Committee. The only other development of potential significance (at least from those with a fear of how the UK might look if compared with its international counterparts) was the adoption by seven major countries of the Ortho test, in addition to Germany which for some time had adopted surrogate screening by testing for ALT. Letter from Allan Follett to customers 22 May 1990 NHBT0016346

838 Letter from Dr Metters to Dr Gunson 5 June 1990 NHBT0000189\_144

839 Memo from John Canavan to Robert Anderson 14 June 1990 NHBT0000061\_145

840 Memo from Dr Metters to Dr Rejman and John Canavan 14 June 1990 DHSC0002497\_115

841 Memo from Dr Rejman to Dr Metters 22 June 1990 p1 NHBT0000061\_148

842 Dr Andrzej Rejman Transcript 11 May 2022 pp127-128 INQY1000204

*the operational matters would need to be carefully considered.*” The main purpose of the meeting, he said, was to reconsider “*the principle*” of Hepatitis C screening.<sup>843</sup>

Professor Zuckerman was of the view that with the FDA decision, the time had come to introduce screening in the UK as a public health measure. The Committee agreed that Hepatitis C screening should be introduced and that it would reduce the number of cases of transfusion transmitted Hepatitis C.<sup>844</sup> The extent of the reduction expected was not captured in the minutes, but Dr Metters stated later that Professor Zuckerman “*spoke in terms of at least 30% of such cases could be avoided, possibly more.*”<sup>845</sup>

However, after discussion the Committee decided that whilst it **would** recommend to ministers that in principle testing should be introduced, there should first be completed a pilot study of the Ortho and Abbott tests to determine which was “*the better test for the Regional Transfusion Centres*”.<sup>846</sup> A draft protocol to carry out the pilot study in the North London, Newcastle and Glasgow RTCs was discussed and agreed, and the working group was tasked with undertaking further investigation into the best approach to counsel donors who tested positive.<sup>847</sup> The anticipated overall timescale for the study was “*approximately four months, after finance had been agreed.*”<sup>848</sup>

The summary recommendation at the end of the meeting was that the UK should introduce Hepatitis C testing but that the decision as to which test to use would be taken following the pilot study on the Ortho and Abbott tests. It was noted that “*the public relations aspect needed to be handled very carefully.*”<sup>849</sup>

When asked whether the assessment of the two tests could have been undertaken concurrently with the implementation of nationwide screening, Dr Rejman told the Inquiry that this was not recommended by the experts on the Committee and noted that the blood transfusion services had concerns about donor volunteers falsely testing positive for a disease for which at the time there was no treatment.<sup>850</sup> Dr Gunson’s evidence in the *A and*

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843 Minutes of ACVSB meeting 2 July 1990 pp2-3 PRSE0000976

844 Professor Zuckerman acknowledged that there would be difficult issues relating to counselling donors due to false positives and that testing would not eliminate the virus but considered that “*it would at least reduce the burden.*” Minutes of ACVSB meeting 2 July 1990 p3 PRSE0000976

845 Memo from Dr Metters to John Canavan 18 December 1990 NHBT0000061\_201

846 Dr Gunson mentioned that Wellcome was also developing a test and it was proposed that frozen library samples should be kept so that donations could be retested later against other tests such as the Wellcome one as they became available. Minutes of ACVSB meeting 2 July 1990 p3 PRSE0000976

847 Proposal for Comparative Study of Anti-HCV Testing Using Ortho and Abbott Test Systems 27 June 1990 NHBT0000042\_038. The plan was that each RTC would perform 3,500 tests, any positive results would be identified and repeated against both the Ortho and Abbott tests and repeatedly positive results would be sent for specialist laboratory confirmatory testing. Consideration of any look-back procedure in relation to positive results was postponed.

848 Minutes of ACVSB meeting 2 July 1990 p4 PRSE0000976

849 Minutes of ACVSB meeting 2 July 1990 p4 PRSE0000976

850 Dr Andrzej Rejman Transcript 11 May 2022 pp132-134 INQY1000204

*Others v National Blood Authority* litigation was that there was a concern about the number of false positive tests, and some concern too that there might be false negative ones.<sup>851</sup>

On 3 July 1990, Dr Metters wrote a briefing for the Chief Medical Officer (“CMO”), Sir Donald Acheson, informing him of the ACVSB’s recommendations and the funding (an estimated £150,000) that would be required for the pilot study:

*“In view of the political and public interest in HCV screening, the confidentiality of ACVSB’s recommendation has been emphasised to all involved. However, should the decision leak, a further interval before HCV screening is introduced can be justified, as the Committee also recommended strongly that the research study mentioned in para 3 [ie the pilot study] above must be undertaken before HCV screening is introduced.”*<sup>852</sup>

Baroness Hooper was told of the ACVSB’s recommendation by a minute dated 7 August 1990, with the indication that a full submission would be provided shortly.<sup>853</sup>

In the meantime, on 4 July 1990, Dr Gunson wrote to Dr Metters suggesting that the next ACVSB meeting (which had been scheduled for October) should take place in mid November after the next Ortho Hepatitis C Symposium. He went on to write:

*“I have already had the Marketing Manager of Ortho on the telephone! I have told him that the study will proceed, but when he asked if a decision had been taken about the introduction of routine screening, I said that I was not prepared to answer that question. There will undoubtedly be further questions asked*

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851 *“The early indications were that the Ortho ELISA test threw up a very large number of false positives ... Matters of concern included the definition of a true positive result and the failure to confirm initial positive reactions using serum with the plasma of the donation, an essential step for quality assurance: the latter suggested that false negative results could occur. SNBTS found differences in sensitivity in the two batches they received ... Unless these could be reliably checked by a supplementary or confirmatory test, the consequences would be very serious.”* Written Statement of Dr Harold Gunson in *A and Others v National Blood Authority* p34 NHBT0000026\_009. This might need to be seen in perspective, though at the April ACVSB meeting, Professor Zuckerman had been “concerned that the Ortho test had a false positive rate of 50 per cent ... He recalled, though, that in the early days of HIV 1 testing the UK had been prepared to accept high false positive rates.” Minutes of ACVSB meeting 24 April 1990 p4 NHBT0000072\_098

852 Memo from Dr Metters to Dr McInnes 3 July 1990 NHBT0000061\_152. Mike Malone-Lee of the NHS Management Executive, who had been copied into Dr Metters’ memo, replied on 9 July 1990, expressing a concern about the resource consequences if the ACVSB were to recommend introducing Hepatitis C screening for all blood donations: Memo from Mike Malone-Lee to Dr Metters 9 July 1990 NHBT0000061\_154. Dr Metters responded on 26 July 1990: “we did have prior warning of the likely cost. You will also be aware of the questioning Ministers have received about why this country has not yet moved on this form of screening when other countries have introduced it for the protection of recipients of donated blood. The question Ministers will have to address is the added protection of blood recipients against non-A, non-B post transfusion hepatitis weighted against the additional cost to BTS. Another factor in the equation is the potential for litigation from cases from non-A, non-B hepatitis who may claim that their illness could have been prevented if the BTS had introduced screening tests that are widely available in other countries.” Memo from Dr Metters to Mike Malone-Lee 26 July 1990 WITN7115016

853 Memo from John Canavan to Elizabeth Baldock 7 August 1990 NHBT0000061\_169. As a matter of fact, no further submission was provided to the minister until after the next ACVSB meeting. Quite why this minute itself was not provided before the parliamentary recess at the end of the July, as might have been done for speed, is unclear.

*elsewhere, and I think that it will be advantageous to have this matter in the public domain under our control as soon as possible.*"<sup>854</sup>

Dr Metters replied on 9 August 1990, expressing “*considerable misgivings*” about delaying the next ACVSB meeting until after the evaluation of the Ortho and Abbott tests would be completed, “*Otherwise, we could be in difficulties should the companies stir up Parliamentary and media interest.*” He added that if the Ortho symposium produced any significant new information there would still be time to take it into account in preparation for testing in the NBTS.<sup>855</sup>

Nevertheless, the next ACVSB meeting was not held until 21 November 1990.<sup>856</sup> In the meantime, on 29 October 1990, Peter Savage wrote to inform Dr Gunson that Ortho was shortly to commence clinical trials of a second-generation ELISA test, with improved sensitivity and specificity, and a second-generation RIBA test incorporating additional antigen bands.<sup>857</sup>

Dr Gunson circulated a report on Phase I of the multi-centre anti-HCV trial to Dr Rejman for the attention of the ACVSB on 30 October 1990.<sup>858</sup>

### **ACVSB meeting 21 November 1990**

The results of the multi-centre trial were discussed at the eighth ACVSB meeting. Dr Gunson reported that both the Ortho and Abbott screening tests were deemed to be satisfactory for routine use from an operational point of view, and the choice of test in each RTC would be influenced by the equipment available.<sup>859</sup>

Dr Tedder presented a preliminary report on the results of the laboratory work he and others had done to check the screened positive samples.<sup>860</sup> There was overall little to choose between the two screening kits. A combination of a RIBA test followed by PCR was suggested as a useful confirmatory service. It was decided that donated blood which screened positive on either test should not be used, but donors would not be informed or counselled until the result was confirmed by supplementary testing at a reference

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854 Letter from Dr Gunson to Dr Metters 4 July 1990 NHBT0000061\_153

855 Letter from Dr Metters to Dr Gunson 9 August 1990 NHBT0000061\_173

856 Nearly six months after the decision had been (finally) made to recommend that testing should in principle be introduced, at the ACVSB meeting of 2 July 1990.

857 Letter from Peter Savage to Dr Gunson 29 October 1990 NHBT0000190\_026. Dr Barbara explained in his written statement to the Inquiry that: “*The second-generation tests contained, in addition to C100-3, two structural antigens, the C22 and C33 antigens. The tests were introduced in early 1991 by the companies which had marketed the first-generation tests. Other manufacturers had independently cloned HCV, one from known carriers of transfusion transmitted non-A non-B hepatitis in London ... I (and others) expected the tests to show significantly improved sensitivity and specificity compared with the first-generation tests because they included structural and extra non-structural antigens and indeed, this proved to be the case.*” Written Statement of Professor John Barbara para 523 WITN6989001

858 Letter from Dr Gunson to Dr Rejman 30 October 1990 ARCH0003392

859 Minutes of ACVSB meeting 21 November 1990 p2 NHBT0000073\_018

860 NBTS HCV Study Preliminary Report 21 November 1990 NHBT0000042\_047

laboratory. Committee members noted that new-generation Ortho and Abbott tests were in the pipeline.<sup>861</sup> Dr Gunson also tabled a paper on the counselling of Hepatitis C positive donors, and noted that the ACTTD would be following up on this. It was concluded that RTCs would decide individually whether to use the Ortho or Abbott test.<sup>862</sup>

The minutes record that “*The Committee agreed that it was important to start screening as soon as practicable as a measure which would further enhance the safety of the blood supply.*” However, when it came to fixing the date from which testing should be introduced, Dr Gunson reported that some RTC directors had requested a six-month preparation period and that although he thought this excessive he said he would need to consult with other directors first. It was agreed by the ACVSB that he would hold off such consultation until the submission had been put to ministers. Dr Metters stressed the importance of a common date of introduction throughout the UK.<sup>863</sup> A separate note by Dr McIntyre, who attended the meeting as an observer on behalf of the SHHD, stated that “*Some wanted to start forthwith but the Chairman suggested that 1 April 1991 might be more realistic.*”<sup>864</sup>

Following the ACVSB meeting, a fuller report of the Ortho and Abbott trial was produced by Dr Edward Follett in Glasgow.<sup>865</sup>

## Ministerial submission and approval

On 30 November John Canavan circulated a first draft of a submission recommending the introduction of anti-HCV screening.<sup>866</sup> A further draft was sent to Dr Metters on 12 December and the latter provided his comments on 18 December 1990, in which he expressed concern that the submission did not properly reflect the views of the ACVSB.

He thought that the way the civil servants had drafted the submission did not echo the enthusiasm of the Committee for its introduction, nor adequately convey the extent and seriousness of the infections which would probably be spared by adopting the test, such that it was unacceptable not to introduce it:

*“2. My major concern is that the submission does not properly reflect the views of ACVSB. The Committee in July reached the conclusion that HCV screening could prevent a significant proportion of post-transfusion hepatitis. You will*

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861 Minutes of ACVSB meeting 21 November 1990 p3 NHBT0000073\_018

862 Minutes of ACVSB meeting 21 November 1990 p4 NHBT0000073\_018, Counselling of HCV Antibody Positive Donors 19 November 1990 NHBT0000042\_050

863 Minutes of ACVSB meeting 21 November 1990 pp3-4 NHBT0000073\_018

864 Note of ACVSB meeting 21 November 1990 p3 SCGV0000210\_117

865 Comparison of Anti-HCV Tests Using Abbott and Ortho Test Kits (A Multi-Centre Trial) Preliminary Report 29 November 1990 NHBT0000190\_050. The final version of the report was produced on 13 December 1990. Comparison of Anti-HCV Tests Using Abbott and Ortho Test Kits (a Multi-Centre Trial) Summary of Results of Phase II of the Trial 13 December 1990 NHBT0000015\_148

866 Memo from John Canavan to recipients in Department of Health 30 November 1990 DHSC0002534\_055, Draft memo from John Canavan to Mike Malone-Lee and others 30 November 1990 DHSC0032367\_080



*remember that Professor Zuckerman spoke in terms of at least 30% of such cases could be avoided, possibly more.*

3. *Furthermore, the Committee's view is that with the existence of the current test procedures, to continue a policy of not screening poses an unacceptable risk to the health of recipients of blood and plasma.*
4. *The Committee recognise that detailed cost benefits of HCV screening could not be quantified. Nevertheless, their unanimous conclusion is that the UK should follow the lead of an increasingly long list of countries ... who have now introduced HCV screening in order to significantly reduce the load of non A – non B post-transfusion hepatitis.*
5. *The submission must convey more clearly ACVSB's position and the Committee's assessment of the benefit/risk balance.”<sup>867</sup>*

The finalised submission, largely altered as Dr Metters suggested, was sent for the attention of Baroness Hooper on 21 December 1990, recommending that screening should be introduced as a public health measure. The submission noted that the ACVSB advised this should happen “as soon as possible” and “firmly recommended the introduction of screening as soon as practicable.”<sup>868</sup>

The introduction of screening was estimated to cost £5.73 million in the first year, with lessening costs subsequently. The benefits of the policy were difficult to quantify financially, but it was thought that it would reduce the risk of litigation. In relation to funding, it was noted that:

*“No special provision has been made for HCV testing in the HCHS [Hospital and Community Health Services] budget. The cost to RTCs would therefore have to be found from the general allocation. Since RTCs will be moving away from direct funding by Regions from 1 April 1991, the cost of screening would have to be reflected in higher handling charges to hospitals for blood supplies. The PHLS who would carry out the supplementary tests would have to find the cost of some £1-£1.5 million by charging RTCs for the service. This too would be reflected in the blood handling charges. In total the screening would add nearly £6 million to the RTCs['] revenue operating costs of approximately £70m pa.”<sup>869</sup>*

This was a reference to a shift in the NHS funding model which took place in 1991, from centralised and area funding provided by the Department of Health and regional health authorities, to an internal market system.<sup>870</sup>

The first argument in favour of screening was that it was “a public health measure which would reduce the incidence of post transfusion hepatitis and the spread of HCV in the

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867 Memo from Dr Metters to John Canavan 18 December 1990 NHBT0000061\_201

868 Memo from John Canavan to Dr Smales and others 21 December 1990 pp1-2 PRSE0004667

869 Memo from John Canavan to Dr Smales and others 21 December 1990 p3 PRSE0004667

870 Baroness Gloria Hooper Transcript 30 June 2022 pp108-111 INQY1000218

*community at large*". The drawbacks listed were the limited predictive value of anti-HCV positive results, the complexity of counselling donors testing positive given the uncertain prognosis, and the financial outlay required pushing up the cost of blood. As for timing, it was submitted that, "*In view of the operational matters that need to be discussed and finalised, it is unlikely that routine screening could be introduced before 1 April 1991.*" The Minister was asked to agree that it should be introduced and that preparations should be made to introduce it "*as soon as practicable.*"<sup>871</sup>

On 31 December 1990, the CMO, Sir Donald Acheson, supported the recommendation by writing on the submission: "*I agree, I consider that a difficult balance has been correctly struck in the circumstances.*"<sup>872</sup>

On 3 January 1991, Dr Rejman wrote to Dr Gunson regarding steps to be taken with regards to Hepatitis C testing in advance of the next ACVSB meeting. He added, "*We are still waiting for Ministers [sic] reply and I shall contact you as soon as this is available.*"<sup>873</sup> Dr Mortimer wrote to Dr Rejman on 9 January raising concerns about who would do and fund the confirmatory RIBA and PCR tests required for the implementation of the screening programme, suggesting that "*Failure to make adequate provision for confirmatory testing would seem to me to call the screening programme into question.*"<sup>874</sup>

On 7 January 1991, at a meeting of the NBTS/SNBTS Liaison Committee it was reported that no decision had been taken by the Department of Health on the implementation or funding of anti-HCV testing.<sup>875</sup> Professor Cash noted that Dr Gunson conveyed his concern that the Department of Health has still not decided on a start date, and it now seemed the earliest possible date would be May or June 1991.<sup>876</sup> Dr Gunson believed the major problem was the Department of Health's disinclination to agree central funding and insistence on cross-charging by increasing the unit cost of blood supplied to hospitals.<sup>877</sup> Despite this uncertainty, arrangements for implementing anti-HCV screening were discussed in detail by the ACTTD at its sixth meeting on 8 January 1991.<sup>878</sup>

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871 Memo from John Canavan to Dr Smales and others 21 December 1990 pp3-4 PRSE0004667

872 The annotated version of the submission is at: Memo from John Canavan to Dr Smales 21 December 1990 DHSC0002498\_096. Baroness Hooper attributes the handwritten note to the CMO. Written Statement of Baroness Gloria Hooper para 31.19 WITN7005001

873 The steps to be taken included discussing counselling and look back procedure at the ACTTD, liaising with regional transfusion directors to prepare for implementation and making arrangements for reference centres to provide confirmatory testing. Letter from Dr Rejman to Dr Gunson 3 January 1991 NHBT0006353

874 Letter from Dr Mortimer to Dr Rejman 9 January 1991 p2 NHBT0000062\_014

875 Minutes of NBTS/SNBTS Liaison Committee meeting 7 January 1991 p2 PRSE0001721

876 Notes of NBTS/SNBTS Management meeting 7 January 1991 p2 PRSE0002858

877 Notes of NBTS/SNBTS Management meeting 7 January 1991 p2 PRSE0002858. Dr Huw Lloyd's evidence to the Inquiry was that Dr Gunson never communicated to him that there was a funding reason holding up the commencement of screening. Dr Huw Lloyd Transcript 9 February 2022 p105 INQY1000183

878 Minutes of UK ACTTD meeting 8 January 1991 pp2-4 NHBT0000073\_028

John Canavan was informed on 16 January 1991 that Baroness Hooper had given her approval for the recommendation to introduce screening as soon as practicable and commented: “*I don’t see that we have any option.*”<sup>879</sup>

### Finding a date for the commencement of testing

John Canavan telephoned Dr Gunson the following week, on 22 January 1991, to inform him that ministerial approval for routine screening had now been granted.<sup>880</sup> Dr Gunson wrote to RTC directors in England and Wales informing them the Department of Health had agreed that routine anti-HCV testing could be put into operation, saying that he sought to ensure testing started simultaneously in all RTCs, and asking them to respond with “*the earliest date that you could commence testing.*”<sup>881</sup> He did not say that the ACVSB had advised testing should commence as soon as practicable.<sup>882</sup>

The dates given in replies were:

- 1 April 1991: Newcastle, Birmingham
- 1 May 1991: Leeds, Sheffield
- 1 June 1991: South London, Brentwood, Manchester/Lancashire, Scotland
- 1 July 1991: Bristol
- 1 August 1991: Liverpool
- 1 October 1991: Cambridge<sup>883</sup>

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879 Memo from Mary Delfgou to John Canavan 16 January 1991 NHBT0000191\_013. As to the delay, Baroness Hooper said that she would not have wanted to make a decision without the CMO’s advice which was received on 31 December. Written Statement of Baroness Gloria Hooper paras 31.22-24 WITN7005001

880 Written Statement of Dr Harold Gunson in *A and Others v National Blood Authority* p36 NHBT0000026\_009

881 Memo from Dr Gunson to regional transfusion directors in England and Wales 22 January 1991 NHBT0000076\_006

882 Dr Lloyd said in his written statement to the Inquiry that had he seen the ACVSB meeting notes of 21 November 1990, he might have considered starting testing at Newcastle RTC earlier than they did (which was, as discussed below, earlier than in other RTCs). Written Statement of Dr Huw Lloyd pp87-88 WITN6935001. In giving his oral evidence to the Inquiry, he affirmed that position and said “*I’m somewhat annoyed that this sort of information wasn’t provided, I’m left in the dark, and I’m sorry about that.*” Dr Huw Lloyd Transcript 9 February 2022 p99 INQY1000183

883 Newcastle – Letter from Dr Lloyd to Dr Gunson 7 February 1991 NHBT0000073\_044, Birmingham – Letter from Dr Fereydoun Ala to Dr Gunson 24 January 1991 NHBT0000073\_032, Leeds – Letter from Dr Angela Robinson to Dr Gunson 29 January 1991 NHBT0016205, Sheffield – Letter from Dr Wagstaff to Dr Gunson 28 January 1991 NHBT0000191\_033, South London – Memo from Tony Martin to Dr Gunson 29 January 1991 NHBT0000073\_041, Brentwood – Letter from Jean Harrison to Dr Gunson 28 January 1991 NHBT0000073\_038 (with Dr Harrison commenting that with “arm-twisting” she could possibly attempt to start in mid-April), Manchester/Lancashire – Letter from Dr Douglas Lee to Dr Gunson NHBT0000073\_042, Scotland – Letter from Professor Cash to Dr Gunson 24 January 1991 NHBT0000073\_033 (Professor Cash made reference to the impact of the Gulf War, as did some other directors, and advised “*in the strongest possible terms*” that testing should not be commenced until after the Gulf conflict was over or at least until such time as they could be confident that blood collection and testing could cope), Bristol – Letter from Dr Ian Fraser to Dr Gunson 24 January 1991 NHBT0000073\_035, Liverpool – Letter from Dr Vanessa Martlew

North London refused to give a date until financial arrangements were clear. Dr Contreras wrote that, “*We are extremely busy with our Business Plans and contracts as well as dealing with the extra workload incurred as a result of the Gulf War and we cannot give anti-HCV screening the priority required by the Department of Health.*”<sup>884</sup> In evidence, she said that she had “*shot from the hip*” in her response because of the workload her service was under.<sup>885</sup> Dr Gunson replied that the Department of Health had not asked for any priority to be given to anti-HCV screening and that he would advise her of the financial arrangements to be made as soon as he could.<sup>886</sup>

On 24 January 1991, Dr Follett wrote to Dr Gunson praising the new generation Abbot Hepatitis C antibody test.<sup>887</sup> In February 1991, Dr Gunson produced a paper reporting on the use of the RIBA II confirmatory assay to assess reactive results from the first-generation Ortho and Abbott study.<sup>888</sup>

On 4 February 1991, Mark Fuller of the NHS Procurement Directorate circulated a minute giving an update on Hepatitis C screening policy. It set out that Ortho second-generation tests were commercially available, Abbott second-generation tests would not be available until March, and that both of these appeared to have far better specificity, meaning fewer “*screen-positive*” tests would need to progress to the more costly (approximately £25) RIBA supplementary test. Competing suppliers Organon Teknika and UBI were bringing new tests to market which should be brought into an evaluation as soon as possible. It was noted that individual RTCs could enter into contracts with test suppliers under their own tendering rules, but “*this may be problematic with respect to any MoD [sic] contract*”. Mark Fuller went on to say that: “*There will be no new money coming from central sources to do this work - all regions will have to fund it in their current round, which many may have fully allocated and therefore delay in National implementation (must be prudently coordinated due to medico-legal implications in future) can only help at present, and above cost-consideration is a distinct disadvantage to manufacturers.*”<sup>889</sup> On 5 February 1991, Dr Gunson wrote to

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to Dr Gunson 24 January 1991 p1 NHBT0000073\_034, Cambridge – Letter from S M McDougall to Dr Gunson 23 January 1991 NHBT0000073\_031, North London – Letter from Dr Contreras to Dr Gunson 22 January 1991 NHBT0000073\_030. Replies cannot be traced for Oxford or Southampton.

884 Letter from Dr Contreras to Dr Gunson 22 January 1991 NHBT0000073\_030

885 Professor Dame Marcela Contreras Transcript 3 December 2021 pp98-100 INQY1000166

886 Letter from Dr Gunson to Dr Contreras 28 January 1991 NHBT0000073\_039

887 Letter from Dr Follett to Dr Gunson 24 January 1991 NHBT0000015\_041. Dr Dow had used the new generation Abbott ELISA to retest the 69 reactive samples from the multi-centre study; only 7 were repeatedly reactive, including the 6 which had previously tested positive under supplemental RIBA and PCR testing. This suggested the new generation test was likely to be more specific and cause fewer false positive results. Dr Gunson replied on 30 January 1991 that he was delighted to hear this. Letter from Dr Gunson to Dr Follett 30 January 1991 NHBT0000015\_042

888 Comparison of Anti-HCV Tests Using Abbott and Ortho 1st Generation Kits (A Multi-Centre Trial) Summary Results of the Trial February 1991 PRSE0003170. Dr Lloyd commented in his written statement to this Inquiry that the RIBA II assay “*appeared to substantially remove the issue of lack of specificity. Once the RIBA II test was available, then in my opinion, the lack of specificity with the 1st generation test would have been much more manageable*”. Written Statement of Dr Huw Lloyd para 143 WITN6935001

889 Memo from Mark Fuller to Eric Evans 4 February 1991 p2 NHBT0000062\_026. Dr Rejman commented on this document in his written statement, saying that his reading was that national

RTC directors in England and Wales following a meeting he attended at the Department of Health, notifying them that the financial proposal was for the costs of Hepatitis C screening (including supplementary testing) to be charged on products issued from the RTCs and borne by the users.<sup>890</sup> He wrote that the date for commencement of screening was to be agreed but he could not see this taking place before June 1991.<sup>891</sup>

On the same day, Dr Pickles wrote to John Canavan:

*“Dr Gunson has been in touch with all the RTCs about starting dates for HCV testing. There are all sorts of problems still, eg exact choice of test, supplies of this, confirmatory testing arrangements, training etc etc. There remains real concern about how the necessary money will get into the system. The starting date he wanted to try out on me was 1 July: would this be too late?*

*My initial reaction was this would be OK. Attempting to go earlier would mean some stragglers would be left behind, the slight delay increased the chance of the finance being sorted out, and with diversion of RTC resources to Gulf-related activities a short time date might not be feasible. Even that date was dependent on blood collection having been stable for the preceding 4 weeks, which should apply provided the ground war is over by then.*

*Do you agree? We will discuss in more detail at ACVSB, I presume.”*<sup>892</sup>

The tone of this correspondence tends to suggest that the sense of urgency apparent in the 21 December 1990 submission to ministers had diminished. Dr Pickles’ evidence to the Inquiry was that the reason for this was because Dr Gunson had received the message from the RTCs that they would need a longer lead time for implementation than anticipated.<sup>893</sup> However, it does not appear that consideration was given to providing the RTCs with support and, if necessary, a challenge to reduce that lead time.

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implementation should be coordinated to avoid possible medico-legal complications in the future, which was a common view. Written Statement of Dr Andrzej Rejman paras 77.1-77.4 WITN4486040. The central message however on a fair reading is that “*delay ... can only help*”, an approach which is certainly not patient-focused. Memo from Mark Fuller to Eric Evans 4 February 1991 p2 NHBT0000062\_026

890 Letter from Dr Gunson to RTC directors 5 February 1991 NHBT0000062\_027. In his written statement in the *A and Others v National Blood Authority* litigation, Dr Gunson said of this letter: “*I should say that, despite the concerns expressed (in particular by Dr. Contreras at the North London RTC), this approach gave rise to no serious difficulties in practice, and I do not believe that it had any consequences for the implementation date eventually achieved. The usual pattern was for the RHA to make funds available until April 1992, after which the costs would be incorporated into the recovery cost for products and services.*” Written Statement of Dr Harold Gunson in *A and Others v National Blood Authority* pp38-39 NHBT0000026\_009. He confirmed this in his oral evidence. Dr Harold Gunson *A and Others v National Blood Authority* Transcript 24 October 2000 pp79-80 NHBT0000146\_001

891 Letter from Dr Gunson to RTC directors 5 February 1991 NHBT0000062\_027

892 Memo from Dr Pickles to John Canavan 5 February 1991 NHBT0000062\_028

893 Dr Hilary Pickles Transcript 12 May 2022 pp172-173 INQY1000205



On 12 February 1991, virologists Drs Mortimer, Tedder, Follett and others met to agree proposed arrangements to be put in place for confirmatory testing at three reference laboratories.<sup>894</sup>

On 15 February 1991, Dr Gunson wrote to RTC directors that the agreed date to implement testing blood donations for anti-HCV was 1 July 1991, “*dependent upon a reasonably normal blood collection pattern at that time.*”<sup>895</sup> He enclosed an updated report on the comparison study of Abbott and Ortho test kits but noted that study of the new generation tests was proceeding.<sup>896</sup>

### **Decision to postpone commencement of screening from 1 July to 1 September 1991**

The ninth ACVSB meeting took place on 25 February 1991. Dr Mortimer reported on developments in the pilot study, now comparing two further candidate screening tests, from Wellcome and UBI, with results from the Ortho and Abbott test kits.<sup>897</sup> Professor Tedder tabled a paper on the new generation Abbott and Ortho tests.<sup>898</sup> The meeting minutes record that “*Members agreed it was important for proper evaluation of the Ortho and Abbott 1&2 tests to be carried out before RTCs decided which test they would adopt.*” The anticipated commencement date remained 1 July 1991.<sup>899</sup>

An internal minute in the Department of Health to Dr Metters on 8 March 1991 shows that funding for additional evaluation of the second-generation tests was being discussed.<sup>900</sup>

On 21 March 1991, Mr J Macleod of the NHS Procurement Directorate wrote to Dr Gunson that the Department of Health had agreed that “*there should be a ‘second-round’ comparative evaluation of Hepatitis C kits at the Newcastle, North London and Glasgow Regional Transfusion Centres (RTCs) with confirmatory testing to be carried out at the University*

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894 Minutes of University College and Middlesex School of Medicine meeting 12 February 1991 NHBT0008073\_002

895 Letter from Dr Gunson to all regional transfusion departments of England and Wales 15 February 1991 p2 NHBT0000191\_077. Dr Contreras replied by letter on 22 February 1991, saying that unless additional funding was made available the start date would be later than 1 July 1991. Letter from Dr Contreras to Dr Gunson 22 February 1991 NHBT0000191\_089

896 Letter from Dr Gunson to all regional transfusion departments of England and Wales 15 February 1991 p2 NHBT0000191\_077, Comparison of Anti-HCV Tests Using Abbott and Ortho 1st Generation Kits (A Multi-Centre Trial) Summary Results of the Trial February 1991 PRSE0003170

897 An Investigation of the Use of the First Generation Ortho and Abbott Anti-HCV EIA Screening Tests in Three Regional Transfusion Centres and of Confirmatory Testing at Three Reference Centres on the Repeatedly Reactive Specimens 14 February 1991 PRSE0003048

898 Further Studies UKBTS Pilot Study 19 February 1991 PRSE0003303

899 Minutes of ACVSB meeting 25 February 1991 pp3-4 PRSE0002280. The 1 July 1991 starting date was also mentioned at a Central Blood Laboratories Authority meeting on 28 February 1991. Minutes of the Central Blood Laboratories Authority Sub-Committee meeting 28 February 1991 p3 NHBT0000065\_034

900 Memo from Alan Barton to Dr Metters 8 March 1991 NHBT0000062\_039. The memo also mentions that Dr Gunson “*doubts whether the Newcastle and Glasgow Centres have the laboratory capability to carry out the additional work now proposed.*” Dr Lloyd, who was then director of the Newcastle RTC, told the Inquiry “*There was absolutely no reason why we couldn’t have done it. And when I read this minute, I was really quite surprised, politely, that this point had been made.*” Dr Huw Lloyd Transcript 9 February 2022 pp118-119 INQY1000183

*College and Middlesex Hospital School of Medicine*”, to be completed by the end of April 1991. The kits to be assessed were from Ortho, Abbott, Organon Teknika and UBI.<sup>901</sup> The letter did not mention any impact on the commencement date for the introduction of general anti-HCV screening.<sup>902</sup>

However, at the next ACTTD meeting on 25 March 1991, the committee was informed that the proposed starting date of 1 July 1991 “*presented difficulties*” because it was “*considered essential*” to evaluate the new generation Ortho and Abbott tests prior to the commencement of routine screening.<sup>903</sup> The committee discussed arrangements to trial these tests using the samples from the pilot study and arrangements for confirmatory testing.<sup>904</sup> The minutes recorded that “*It was agreed that testing of blood and plasma donations would commence on a specified date*”, but no date was specified.<sup>905</sup>

The ACTTD minutes do not suggest there was any funding-related reason for introducing this further pilot stage. It had been decided by then that RTCs should recoup the costs of screening by increasing charges for blood such that the cost burden of testing fell on the

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901 Letter from J Macleod to Dr Gunson 21 March 1991 NHBT0000191\_115

902 Meanwhile, a draft circular on changes to blood handling charges circulated to recipients in the Department of Health on 20 March 1991 stated: “*Ministers have agreed that screening for HCB should be introduced as a public health measure. A starting date of 1 July has been set. Failure to introduce screening would pose an unacceptable risk to the recipients of blood ... A choice of screening tests will be available by 1 July, some in second generation form. Individual RTCs will choose the testing kit they think most suitable.*” Memo from John Rutherford to Regional General Managers 20 March 1991 p5 WITN7005043. The finalised version of this circular sent by Mike Malone-Lee in May 1991 referred instead to a likely date of 1 September 1991. Letter from Mike Malone-Lee to Regional General Managers of Special Health Authorities May 1991 p1 NHBT0000192\_001

903 Minutes of UK ACTTD meeting 25 March 1991 p2 NHBT0000073\_063. Professor Cash’s evidence to the Penrose Inquiry was: “*Some very distressing conversations with Dr Gunson over the weekend before the ACTTD meeting of the 25 March 1991 left me in no doubt that, despite his letter of the 22 January to NBTS Directors signalling the commencement of forward planning for a full HCV donation screening start day ... this had been reversed by DHSS in early February 1991 against Dr Gunson’s wishes and without consultation with him or other members of ACVSB. Dr Gunson also insisted that SHHD had been party to this decision and that both Departments of Health were extremely anxious that there would be no difficulties at the 25 March ACTTD meeting. There was no reason at all why we could not have introduced screening using the first generation kits.*” Written Statement of Professor John Cash to the Penrose Inquiry pp11-12 PRSE0002529. In direct contrast, Dr Gunson gave evidence in the *A and Others v National Blood Authority* litigation that on 25 March 1991, no decision had yet been made, even an implicit decision, to put back the date when screening would commence. Dr Harold Gunson Transcript in *A and Others v National Blood Authority* 24 October 2000 pp90-91 NHBT0000146\_001

904 Minutes of UK ACTTD meeting 25 March 1991 pp2-3 NHBT0000073\_063. A letter from Dr Mortimer about confirmatory testing was tabled. Letter from Dr Mortimer to Dr Gunson 22 March 1991 NHBT0000043\_077. Dr Contreras attended the meeting but afterwards discussed the minutes and his letter with colleagues at the North London Blood Transfusion Centre and wrote to Dr Gunson on 22 April 1991 to protest that the proposed procedure for supplementary testing, counselling and referral was “*extremely complicated and astronomically expensive.*” She accepted that the NBTS had no option but to introduce screening but said “*we are going over the top with this testing for a virus that has not been shown by anybody to cause immense health care problems in the U.K.*” Letter from Dr Contreras to Dr Gunson 22 April 1991 p1, p3 NHBT00006421\_002. Dr Gunson replied on 1 May 1991 that he hoped they would “*eventually arrive at sensible conclusions.*” Letter from Dr Gunson to Dr Contreras 1 May 1991 p2 NHBT0000192\_005. Professor Contreras explained to the Inquiry that the proposal for confirmatory testing was “*totally impractical and expensive*” and that the issue was quickly resolved. Professor Dame Marcela Contreras Transcript 3 December 2021 pp105-107 INQY1000166

905 Minutes of UK ACTTD meeting 25 March 1991 p2 NHBT0000073\_063

NHS (and private sector providers) generally.<sup>906</sup> Further, Dr Gunson's evidence in the *A and Others v National Blood Authority* litigation was that in the event, the regional health authorities did agree to fund the initial outlay required by services to implement screening.<sup>907</sup> Professor Cash's evidence to the Penrose Inquiry was that Dr Gunson had told him at this time that funding issues in England were the source of the delay and that "*this was a device to give the Department of Health more time, more space, to resolve these very difficult financial problems that they had.*"<sup>908</sup> Funding does not appear to have presented a challenge to the SNBTS.<sup>909</sup>

Following the ACTTD meeting, on 3 April 1991 Dr Gunson wrote to all RTC directors in England and Wales, and to Professor Cash, advising that the Department of Health had agreed a "*second-round*" evaluation of anti-HCV test kits (which, he said, was "*undoubtedly in our interest*") and it would no longer be possible to introduce Hepatitis C screening on 1 July 1991. Instead, he proposed to aim for a 1 September 1991 start date.<sup>910</sup>

On 4 April 1991, Dr Gunson replied to Mr Macleod at the NHS Procurement Directorate stating that the timing of the "*second-round*" evaluation of anti-HCV test kits, which Mr Macleod had proposed should take place by the end of April 1991, had "*slipped because of the unavailability of test kits.*" He said that the Ortho second-generation tests had arrived within the last few days and it was unlikely that the Abbott test kits would be available until the middle of April, and that "*In order to accommodate the slippage I have, with the agreement of Dr. Metters, postponed the introduction of routine anti-HCV screening until 1st September 1991.*"<sup>911</sup>

On 5 April 1991, Professor Cash wrote to Dr Gunson that the recent development (ie the additional pilot stage) leading to a start date in September 1991, "*has the SNBTS Directors' fullest support.*"<sup>912</sup> This was not reflective of the view of David McIntosh of SNBTS however. His evidence to this Inquiry was that: "*misplaced desire for Anglo-Scottish solidarity was the clear cause of the unnecessary delays in the universal implementation of HCV testing in Scotland. I believed then, and remain convinced, that it was utterly inappropriate and*

906 Written Statement of Baroness Gloria Hooper para 31.36 WITN7005001

907 In his oral evidence in the *A and Others v National Blood Authority* litigation he said that "*From September 1991 until April 1992, the Regional Health Authorities funded the testing, with one exception, where they only partially funded it, and after April 1st 1992, the cost of testing was put on to the price of the products.*" Dr Gunson Transcript in *A and Others v National Blood Authority* 24 October 2000 pp79-80 NHBT0000146\_001. See also his written statement: Written Statement of Dr Harold Gunson in *A and Others v National Blood Authority* March 2000 p38 NHBT0000026\_009

908 Professor John Cash Penrose Inquiry Transcript 1 December 2011 p169 PRSE0006072. Professor Cash said the same funding problem did not arise in Scotland, and his own strong view was that the second-generation tests could be evaluated once screening had already commenced using the first-generation tests. Despite this, as discussed below, he was unhappy when Dr Lloyd commenced screening in Newcastle before the NBTS/SNBTS planned joint start date of 1 September 1991.

909 Written Statement of David McIntosh paras 269-270 WITN3523001

910 Letter from Dr Gunson to all RTC directors in England and Wales 3 April 1991 NHBT0000073\_065

911 Letter from Dr Gunson to Mr Mcleod 4 April 1991 NHBT0000015\_056

912 Letter from Professor Cash to Dr Gunson 5 April 1991 NHBT0000191\_133. Professor Cash told the Penrose Inquiry that this letter was the product of a reconciliation between himself and Dr Gunson after they had fallen out over the postponement of screening. Professor John Cash Penrose Inquiry Transcript 1 December 2011 pp174-175 PRSE0006072

*resulted in a sub-optimal outcome in terms of blood and plasma product safety, to the detriment of patients in Scotland.”*<sup>913</sup>

The NBTS National Management Committee met on 16 April 1991, and noted that the ACTTD had received conflicting advice on the range of available confirmatory tests available. Dr Gunson offered to prepare a policy paper for the Committee after the next meeting of the ACVSB, by which time the evaluation of second-generation tests might have been completed.<sup>914</sup> The minutes do not record any controversy or dissent in relation to the delayed commencement of general screening.

In giving his evidence to the Inquiry, Dr Rejman explained that the initial date for implementation was fixed according to the replies from the RTCs as to “*how quickly can they actually get their show on the road.*” However, when the second-generation tests came out, they needed to be evaluated to see if they worked better. They were expected to generate fewer false positive results, with the important benefit that this would increase the volume of available donations.<sup>915</sup> Dr Pickles also recalled “*that people were concerned and keen to push on as fast as was feasible, and frustrated that, really, the service needed longer to be ready to introduce this.*”<sup>916</sup> However, there is little evidence that the public health benefit of testing was kept in the forefront of decision-making during this period. During every day, week and month of delay, more people were receiving blood transfusions and blood products from donations which had not been tested for anti-HCV, meaning that additional transmissions were known to be occurring.

As to whether an evaluation of the second-generation tests was really needed before screening could commence, it is clear that an evaluation could have been conducted concurrently with general screening. Dr Huw Lloyd’s evidence to the Inquiry, in keeping with his views at the time, was that running a trial on the more effective second-generation tests instead of starting general screening, was illogical.<sup>917</sup> His service could have started testing as early as January 1991, as soon as Department of Health approval was given.<sup>918</sup> Dr Gunson gave evidence in the *A and Others v National Blood Authority* litigation that: “*I accept that it would have been possible to adhere to the earlier date [of 1 July 1991], using the second generation test and collecting data from all RTCs until the second generation tests had been fully evaluated. With hindsight, I think that it would have been better if we had done so.*”<sup>919</sup> Dr Barbara’s written evidence to this Inquiry was that:

*“we needed to complete the second-round comparative evaluation of test kits and gain more experience in confirmatory assays (RIBA and PCR) before reliable*

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913 Written Statement of David McIntosh para 288 WITN3523001

914 Minutes of National Directorate of the NBTS National Management Committee meeting 16 April 1991 p9 NHBT0000191\_144

915 Dr Andrzej Rejman Transcript 11 May 2022 pp136-138 INQY1000204

916 Dr Hilary Pickles Transcript 12 May 2022 p183 INQY1000205

917 Written Statement of Dr Huw Lloyd para 146 WITN6935001

918 Dr Huw Lloyd Transcript 9 February 2022 p148 INQY1000183

919 Written Statement of Dr Harold Gunson in *A and Others v National Blood Authority* p41 NHBT0000026\_009



*and more accurate and specific testing could begin with workable methods for determining the infection status of the donor. It is unsafe to inform blood donors of a false positive test that would ‘label’ them as (probably) infected hence the need for confirmatory testing.”*<sup>920</sup>

He went on to say “*My own view remains that scientifically it was more appropriate to do the trialling before mass use for donor screening but with hindsight I believe that it would have been better to have tried to introduce screening with second-generation tests plus RIBA sooner.*”<sup>921</sup> However, when asked in evidence “*Was there any reason why the testing of the second generation tests couldn’t have occurred in parallel with the introduction of testing for all donations?*” he replied “*In hindsight I believe not. I have to add, provided we got the RIBAs, yes.*”<sup>922</sup>

When asked why it was thought necessary to undertake the evaluation of second-generation tests, Dr Contreras’ answer to the Inquiry was that in hindsight, she thought testing could have started in July 1991<sup>923</sup> or earlier, once the second-generation tests were available.<sup>924</sup>

Implementation of the less specific first-generation tests in the first instance, with evaluation and introduction of the second-generation tests undertaken concurrently with a national screening programme, would have avoided some additional infections with Hepatitis C. Once the decision was taken that the first-generation tests ought to be implemented, the entry to market of new and better second-generation tests ought not to have been a reason for delay.

It appears that the responsible minister, Baroness Hooper, was not told of the decision to postpone the introduction of screening to September. She thought she ought to have been.<sup>925</sup>

## Dr Huw Lloyd

A different approach was taken by Dr Lloyd, director of the Northern Regional Health Authority National Blood Transfusion Service based at Newcastle.

On 20 July 1989, Dr Lloyd had written to his director of management services explaining that a new test had been developed for non-A non-B Hepatitis: “*Now that this test is available I suspect that pressure will mount fairly rapidly for this test to be introduced in this country.*”<sup>926</sup>

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920 Written Statement of Professor John Barbara paras 566-567 WITN6989001

921 Written Statement of Professor John Barbara para 576 WITN6989001

922 Professor John Barbara Transcript 26 June 2022 p71 INQY1000176

923 Professor Dame Marcela Contreras Transcript 3 December 2021 pp104-105 INQY1000166

924 Professor Dame Marcela Contreras Transcript 3 December 2021 p110 INQY1000166

925 Baroness Gloria Hooper Transcript 30 June 2022 p115 INQY1000218

926 Letter from Dr Lloyd to A Garland 20 July 1989 p1 NHBT0000188\_008. He went on to say that Dr Gunson had indicated services would have to fund the introduction of testing themselves and that at a cost of £1.50 per sample, this would add £200,000 to their region’s annual bill. Together with the loss of about 600 donations and the requirement for counselling to be provided for those donors, he anticipated the total cost to be in the region of £250,000 in the first year.



He explained that the purpose of his letter was to highlight the situation, “*as we do not know at what stage we might be instructed to introduce this new test.*”<sup>927</sup>

On 6 February 1991, he wrote to colleagues saying that Dr Gunson was looking for all red blood cells available for issue to be Hepatitis C negative by 30 June 1991, which would mean starting testing some weeks in advance.<sup>928</sup> The next day, he wrote to Dr Gunson that the Northern Region Blood Transfusion Service would be able to start testing from approximately 1 April 1991, and that first-generation Abbott tests could be obtained without any problems. He added, “*If the introduction could be associated with the availability of a second generation test which has been shown to have improved specificity, then this would be particularly advantageous.*”<sup>929</sup>

In April 1991, having received the notification that the date for nationwide commencement of screening had been postponed from 1 July to 1 September 1991,<sup>930</sup> Dr Lloyd took the decision that his Newcastle RTC should begin anti-HCV testing unilaterally.<sup>931</sup> He had a telephone call with Dr Gunson on 29 April 1991, during which he said that he had commenced routine screening in the previous week using the second-generation Abbott anti-HCV test.<sup>932</sup>

Dr Gunson wrote to Dr Lloyd following their call, expressing displeasure that Dr Lloyd had acted without discussing the matter first with him and the other RTC directors.<sup>933</sup> In his letter, Dr Gunson complained that he had kept Dr Lloyd fully informed of the national policy with respect to anti-HCV testing, that there were still other matters which had not yet been concluded in relation to confirmatory testing and management of donors, and that since he was unaware that the Newcastle RTC was preparing to commence screening in advance of other centres, he had thought “*we have ample time to sort out the implications for donors in the implementation of this test.*”

On 30 April 1991, Dr Gunson reported Dr Lloyd’s decision to the SNBTS/NBTS Liaison Committee.<sup>934</sup> He also informed the Department of Health: an internal minute dated 30 April

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927 Letter from Dr Lloyd to A Garland 20 July 1989 p2 NHBT0000188\_008

928 Memo from Dr Lloyd to Richard Masterman 6 February 1991 NHBT0000191\_060

929 Letter from Dr Lloyd to Dr Gunson 7 February 1991 NHBT0000073\_044. Dr Lloyd said when giving evidence that his RTC was “*ready to go*” with the first-generation test. Dr Huw Lloyd Transcript 9 February 2022 p108 INQY1000183

930 Which he said in evidence made him upset and unhappy. Dr Huw Lloyd Transcript 9 February 2022 p109 INQY1000183

931 A letter dated 25 April 1991 to Dr Lloyd from Dr Arthur Codd, consultant virologist at the PHLS in Newcastle stated “*I understand that you will soon be screening blood donors for hepatitis C in advance of other transfusion centres*” and inquired as to his proposed start date. Letter from Dr Codd to Dr Lloyd 25 April 1991 NHBT0000191\_159

932 Letter from Dr Gunson to Dr Lloyd 29 April 1991 NHBT0034547. Dr Lloyd told the Inquiry that Dr Gunson was “*beside himself*” during the call. Dr Huw Lloyd Transcript 9 February 2022 p125 INQY1000183

933 Letter from Dr Gunson to Dr Lloyd 29 April 1991 p1 NHBT0034547. Dr Gunson referred also to the fact that the National Procurement Directorate had been negotiating with several companies to conclude “*the best possible price for the tests on a UK basis.*”

934 Minutes of SNBTS/NBTS Liaison Committee meeting 30 April 1991 p2 PRSE0004478

1991 noted that *“This action has caused problems in that the other major competitor company feels disadvantaged, and has also caused problems in Scotland.”*<sup>935</sup>

Dr Lloyd replied to Dr Gunson setting out the reasons for his decision on 1 May 1991:

*“When a common date of 1st July was circulated some time ago, I made a decision to start testing in April 1991 so that we could be assured that not only were all issues of blood and blood components negative for the antibody but that all units transfused from that date were negative.*

*I set up the internal arrangements and made it clear that testing would start in the Region in the early part of the year. The decision to start testing was based on a test that was not perfect, but nevertheless, it was available and it did detect a group of people who appeared to be positive for the Antibody. The comparative study of the Abbott and Ortho kits (first generation), was not going to influence my decision as to whether or not to start testing.*

*The next round of comparative trials which encompasses other manufacturers kits as well as second generation kits from Abbott and Ortho when started was not going to be completed in time to allow this Centre to meet the July deadline, even on the original schedule. The change in date based on a further delay in the completion of the next round of evaluations would have delayed the introduction of testing (all transfused units negative) by several months, possibly taking us to November of this year.*

*If during that period anyone becomes infected and subsequently takes action, in my opinion, I would have had no defence. We had the wherewithal to test, including kits, equipment and staff and we had agreed to start previously. The delay is thus administrative and that not only forms no basis for a defence or a mitigation but also I think aggravates the situation.*

*I have therefore proceeded on the basis that all units available for transfusion from 1st July will have been tested.”*<sup>936</sup>

On 2 May 1991, Dr Lloyd wrote to all RTC directors informing them of his decision.<sup>937</sup> He decided to keep the original date for implementation because, in his view, *“not to test now that we have the ability to test would be indefensible under the current Product Liability Legislation.”* He stated that he was aware that other directors might take a different stance on the question of liability but did not consider that Newcastle’s decision to test would *“materially alter that judgement.”* He inquired whether other RTCs were currently carrying out additional surrogate testing, and if so, what criteria they applied.

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935 Memo from Dr Rejman to Dr Metters 30 April 1991 p1 NHBT0000062\_054. Dr Rejman briefed Baroness Hooper on the same date: Memo from Dr Rejman to Baroness Hooper 30 April 1991 NHBT0000062\_053. No reference was made to any slippage in the proposed simultaneous start date.

936 Letter from Dr Lloyd to Dr Gunson 1 May 1991 NHBT0000074\_010

937 Letter from Dr Lloyd to all RTC directors 2 May 1991 NHBT0000074\_014

This caused a furore. Dr Lloyd received letters of objection from Dr Contreras,<sup>938</sup> Dr Mitchell,<sup>939</sup> Dr Boulton,<sup>940</sup> and Professor Cash, who said his unilateral action was “*disgraceful and mischievous*”. He added:

*“Your action on HCV donation testing reveals, beyond doubt, that the NBTS is descending into a position now more accurately described as chaos. It seems to be dog eat dog time, Huw, and I would suggest it is also time when you should remove the heading National Blood Transfusion Service from your headed notepaper and time for you and any of your staff who serve UK BTS and/or NBTS committees and working parties to be excluded.”*<sup>941</sup>

A meeting of the Northern Division of the NBTS minuted their “*dismay*”.<sup>942</sup>

I cannot let this pass without comment. Dr Lloyd’s motivation, as he made clear, was protecting the health of those who received blood transfusions in the North East. He put the safety of recipients first. That was indisputable, and was known at the time. The tirade of highly unpleasant and intemperate abuse from colleagues about this is one of the most disturbing aspects of the introduction of anti-HCV screening. The matter which most appeared to upset them was that it had been generally agreed – by Dr Gunson on behalf of RTCs in England and Wales, and Dr Cash and the SHHD in Scotland – that screening would begin at one and the same time across the country, and it was Dr Lloyd’s “*breaking ranks*” with this that merited these harsh words. There was no justification for such remarks (particularly because the policy of “*go at the pace of the slowest*” was what, effectively, universal coincidence of timing amounted to). There was a debate to be had, which could and should have been conducted rationally. It might, for instance, then have been pointed out that the fact that a number of centres were already testing (because they were conducting “*pilot trials*”) might have suggested that all centres were not, in practical terms, moving as one when it came to a start date. It should also have been realised that if patient safety was to be prioritised, Dr Lloyd’s approach was indisputably right. It was the

938 Letter from Dr Contreras to Dr Lloyd 3 May 1991 NHBT0000192\_009, which said “*a national approach might well have prompted the Department of Health to provide appropriate funding for testing.*” In evidence, Dr Contreras said “*I am really sorry to have written this letter, because I think we could have introduced anti-HCV testing in July.*” Professor Dame Marcela Contreras Transcript 3 December 2021 p109 INQY1000166. On receipt of her letter, Dr Lloyd wrote to Dr Gunson on 9 May 1991 asking “*whether there was in fact a strategy which involved delaying the introduction of tests whilst awaiting central funding for this test.*” Letter from Dr Lloyd to Dr Gunson 9 May 1991 NHBT0000074\_026. He told the Inquiry he did not recall receiving a response from Dr Gunson. Dr Huw Lloyd Transcript 9 February 2022 p141 INQY1000183

939 Letter from Dr Mitchell to Dr Lloyd 7 May 1991 NHBT0000074\_017

940 Letter from Dr Boulton to Dr Lloyd 8 May 1991 NHBT0000074\_021. Dr Boulton’s evidence to the Inquiry was that “*I now feel quite strongly that Huw was right although at the time, because I didn’t know the full picture, I felt that he was -- by breaking ranks, was disrupting the Service and introducing a sort of postcode lottery for donors and patients living in certain areas.*” Dr Frank Boulton Transcript 4 February 2022 pp152-154 INQY1000181

941 Letter from Professor Cash to Dr Lloyd 7 May 1991 NHBT0000074\_019. Dr Lloyd defended himself in a letter of reply dated 9 May 1991. Letter from Dr Lloyd to Professor Cash 9 May 1991 NHBT0000192\_031. Professor Cash told the Penrose Inquiry that he very much regretted having been “*so tough on him*”. Professor John Cash Penrose Inquiry Transcript 1 December 2011 pp179-180 PRSE0006072

942 Minutes of the Northern Division of the NBTS meeting 13 June 1991 p3 NHBT0071757

approach which would lead to a lower number of infections. It is worth noting that some 20 years earlier universal screening for Hepatitis B had begun when it was known that the tests were likely to identify only around 30% of the infected units; when better tests were highly likely to be on their way (and were adopted in due course); and when those identified as positive donors would have to be counselled. It is also worth recording that in evidence Dame Marcela Contreras reflected back that there was, in reality, little good reason for delaying the start of testing at least at this stage: a policy of waiting when it had already been agreed to introduce a test was always going to result in unnecessary infections, and undoubtedly did so.<sup>943</sup>

In response to Dr Lloyd's decision, Professor Cash suggested that the evaluation of second-generation tests might be modified to accommodate the screening programme in Newcastle.<sup>944</sup> Dr Gunson wrote to all RTC directors on 9 May 1991 reaffirming the 1 September 1991 start date but announcing that Dr Lloyd's "*premature introduction of the test*" could be used to extend the evaluation trial. While Newcastle was using the second-generation Abbott test, the Department of Health had agreed that Leeds and Liverpool RTCs should trial the second-generation Ortho test.<sup>945</sup> He also included a briefing note in case of press inquiries, which stressed the importance of selecting tests with proven reliability.<sup>946</sup> This was described in the meeting of the NBTS' Northern Division as Dr Gunson having salvaged the situation "*in such a masterly fashion by setting up an extension of the original valuation study to look at the performance of the 2nd generation anti-HCV test kits.*"<sup>947</sup> Dr Gunson later explained that the practical effect of these "expanded trials" was that screening was introduced around the beginning of June in four RTCs: Leeds, Liverpool, Sheffield and Bristol.<sup>948</sup>

On 18 June 1991, Dr Lloyd recorded that "*My only regret is that we didn't introduce [HCV testing] earlier. The coordinating activity of the National Directorate appears to have provided us with a lowest common denominator approach rather than a best possible approach.*"<sup>949</sup> On 24 June 1991, he wrote to Dr Gunson reaffirming that he felt comfortable that his decision was correct and defensible. He stated that, "*The fact that many other countries have been testing for about a year now and in some cases longer, makes the U.K. position look increasingly unrealistic and very hard to defend*". The July date had already, he said, been a compromise "*based not on the best interests of patients but on convenience for*

943 Professor Dame Marcela Contreras Transcript 3 December 2021 p109 INQY1000166. A number of those who gave evidence to the Inquiry were infected with Hepatitis C during the time that the debate ran about which test to use, rather than using either or both.

944 Letter from Professor Cash to SNBTS colleagues 8 May 1991 PRSE0002761, Letter from Professor Cash to Dr Gunson 8 May 1991 NHBT0000074\_024

945 Letter from Dr Gunson to all RTC directors in England and Wales 9 May 1991 p1 NHBT0000192\_024

946 Letter from Dr Gunson to all RTC directors in England and Wales 9 May 1991 p3 NHBT0000192\_024. The same briefing note was circulated internally at the Department of Health: Minute from J C Dobson to John Murphy and others 9 May 1991 NHBT0000062\_060. Dr Lloyd described the "*extended test*" as a "*face saving exercise*". Written Statement of Dr Huw Lloyd para 149 WITN6935001

947 Minutes of Northern Division of the NBTS meeting 13 June 1991 pp3-4 NHBT0071757

948 Written Statement of Dr Harold Gunson in *A and Others v National Blood Authority* March 2000 pp40-41 NHBT0000026\_009

949 Memo from Dr Lloyd 18 June 1991 NHBT0000192\_092

*certain Transfusion Centres.*” He argued that although the evaluation of second-generation test kits had not yet been completed, UK screening should now start “*come what may*’.”<sup>950</sup>

On 18 July 1991, Dr Lloyd wrote to Professor Cash. By this time they had resolved their differences in person and the letter was cordially expressed. However, Dr Lloyd reiterated his concern that the UK was “*dragging its feet over testing*” and was running the risk of “*accepting the lowest common denominator*” approach.<sup>951</sup>

Dr Lloyd was right, his detractors were wrong (and unfair in their attitude towards his decision), because his decision protected recipients of donor blood in his region from avoidable Hepatitis C transmission from an earlier date. Although a coordinated UK-wide approach no doubt had some advantages, including in having a joint negotiating position with companies marketing the tests,<sup>952</sup> the benefit of uniformity for its own sake did not justify additional infections, serious illness and deaths in areas which were in a position to commence testing earlier. Attempting to avoid a “postcode lottery” is not sensible if the result is that almost everyone loses. Having piloted the first-generation and second-generation tests in a limited number of services meant that, already by this stage, anti-HCV positive donor blood had been removed from circulation in some regions and not in others. There was insufficient basis for the Department of Health, SHHD, NBTS and SNBTS to prioritise coordination instead of allowing RTCs to commence testing as soon as arrangements could be put in place to do so.

### **ACVSB meeting 21 May 1991**

At the tenth ACVSB meeting on 21 May 1991, Dr Gunson spoke about the results of the second-generation Ortho and Abbott, Organon and UBI trials. Dr Mitchell commented on results from use of the Abbott II test in Glasgow. The committee noted that they were not due to meet again before the introduction of routine Hepatitis C screening. It was decided that Ortho II, Abbott II or UBI tests could be used for initial screening, at the choice of individual RTCs, guided by trial results so far. Dr Lloyd’s “*unilateral action*” was regretted, but Dr Gunson suggested that it could be “*used as an extension of the trial*.”<sup>953</sup>

On 3 June 1991, in the Department of Health, Mr Canavan wrote to Mike Malone-Lee: “*As for HCV testing, I don’t think anyone was under any illusions but that it was marginal in terms of cost benefit. But this is true of other NHS interventions. However, the litigation*

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950 Letter from Dr Lloyd to Dr Gunson 24 June 1991 NHBT0000076\_009

951 Letter from Dr Lloyd to Professor Cash 18 July 1991 PRSE0001183

952 Joint statement by Dr Barbara and Dr Gunson *Unilateral introduction of anti-HCV testing at Newcastle RTC in April 1991* 17 March 1991 NHBT0088813\_002. Dr Lloyd said in evidence that this statement in prioritising the interests of “*the Service as a whole*”, overlooked the interests of patients and the safety of blood. Dr Huw Lloyd Transcript 9 February 2022 pp154-155 INQY1000183

953 Minutes of ACVSB meeting 21 May 1991 pp2-4 NHBT0000042\_080, Agenda for ACVSB meeting 21 May 1991 PRSE0004451. The ACVSB were also provided with minutes of the virologists’ ad hoc meeting on 12 February 1991; the cover sheet is at: Letter from Dr Mortimer to Dr Rejman 3 May 1991 p4 NHBT0000192\_010. The minutes, referred to above, are at: Minutes of University College and Middlesex School of Medicine meeting 12 February 1991 NHBT0008073\_002



*factor, the introduction of testing elsewhere in Europe and the prospect of EC harmonisation of licensing requirements for blood products stacked up in favour of testing.*<sup>954</sup>

On 10 June 1991, the ACTTD met and discussed, among other matters, the protocol for handling donations and donors who repeatedly tested positive on initial ELISA screening. It was agreed that confirmatory testing should be carried out using a second-generation RIBA test; the committee thought more information was needed on PCR testing.<sup>955</sup> Dr Mortimer followed up by suggesting a confirmatory testing pilot during September and October 1991, which was accepted by the RTC directors.<sup>956</sup> On 11 June 1991, Dr Brian McClelland, Director of the Edinburgh & South East Scotland Blood Transfusion Service, wrote to Professor Cash:

*“HEPATITIS C TESTING*

*I propose to request that this item be discussed at some point when we are together for the forthcoming Board Meeting. The recent newspaper and television attention has emphasised the importance of being able to make enhance and positive statements about the completeness of the safety testing carried out on our blood donations; the fact that some Centres are carrying out testing, albeit on a large pilot study basis, leaves us in a very exposed position.*

*I would like to be reassured that we are taking the correct decision, both professionally and medical legally, to stay in line with the positions of the majority of English RHA’s; I think this is in fact what we are now doing rather than abiding by a Department of Health policy because it seems to me that de facto, may no longer be a Department of Health policy in this area.”*<sup>957</sup>

The SNBTS held a management board meeting on 11 and 12 June 1991. The minutes record that it was agreed that anti-HCV testing was to begin on 1 September 1991.<sup>958</sup> According to Professor Cash, there was at that meeting a “*hotly contested debate*” on a proposal that the SNBTS should emulate Newcastle and establish full screening as soon as possible. The proposal was defeated.<sup>959</sup> A letter from Professor Cash to Dr Gunson referred to the meeting as “*near disaster*.”<sup>960</sup>

954 Memo from John Canavan to Mike Malone-Lee 3 June 1991 NHBT0000192\_076. In evidence, John Canavan stated that was a reference to the economic cost-benefit and not the public health benefit. John Canavan Transcript 22 September 2022 pp79-80 INQY1000244

955 Minutes of UK ACTTD meeting 10 June 1991 pp2-4 NHBT0000044\_003

956 Fax from Dr Mortimer to Dr Gunson 12 June 1991 NHBT0000192\_084, Draft letter from Dr Mortimer, Dr John Craske and Professor Tedder to all RTC directors in England and Wales NHBT0000192\_085, Letter from Dr Gunson to Dr Mortimer 17 June 1991 NHBT0000192\_089

957 Letter from Dr McClelland to Professor Cash 11 June 1991 PRSE0001759

958 Minutes of SNBTS Management Board meeting 11-12 June 1991 p4 PRSE0000298

959 Written Statement of Professor John Cash to the Penrose Inquiry p12 PRSE0002529. The Glasgow RTC, the largest in Scotland, was evaluating the Abbott test: Dr Gunson *Comparison of Anti-HCV Tests* 3 July 1991 NHBT0000062\_079

960 Letter from Professor Cash to Dr Gunson 17 June 1991 NHBT0000192\_091. In his written statement to the Penrose Inquiry he said it “*could have triggered a descent into chaos*.” Written Statement of Professor John Cash to the Penrose Inquiry p12 PRSE0002529

On 26 June 1991, Professor Jean-Pierre Allain of the Cambridge RTC wrote to Dr Gunson, Dr McClelland in Edinburgh and all RTC directors in England and Wales to propose a study testing for anti-HCV in samples from recipients of blood transfusions, expressing the view that *“We could take great advantage of the two months remaining before the implementation of the HCV antibody screening”*.<sup>961</sup> Dr Jean Harrison, Director of the North East Thames RTC, replied on 1 July 1991 declining to participate:

*“I have tried to put myself in the position of a patient, receiving a blood transfusion and then being called to see the GP six months later. Following this, I, the patient, might be told that I have an infection with Hepatitis C and I am given information about the consequences of that. I would then ask my GP whether the infection was due to the blood transfusion and the GP would tell me that it definitely was due to the blood transfusion (we would even have the information that the patient was negative for HCV antibodies prior to the transfusion). I would then ask my GP whether, since he was able to test me for this infection, the donors of the blood could have been tested for this infection. The answer to that question also has to be yes and even if the GP informs the patient that testing antibodies to the HCV virus had only commenced in September whereas the transfusion had taken place in July or August, the patient could still argue that testing for antibodies to HCV could have started before September and indeed, testing in the Newcastle BTS did start before September. If I was the patient, I would then be tempted to seek the advice of my solicitor and with some justification.”*<sup>962</sup>

Professor Allain replied on 1 July 1991, disagreeing with her analysis of the ethical position and asking her to reconsider. He asked, *“If your reasoning is true, why don’t you start screening all your donors now? If you don’t you are just as much open to litigation until September 1st, whether or not you enter the study.”*<sup>963</sup> She replied that she did think there was exposure to possible litigation but unfortunately at the present time the Brentwood RTC did not have the funding, equipment or staff training to commence testing immediately.<sup>964</sup>

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961 Fax from Professor Allain to multiple recipients 26 June 1991 NHBT0000050\_016

962 Letter from Dr Harrison to Professor Allain 1 July 1991 p1 NHBT0000075\_003. Dr Harrison commented on this letter in her written statement to the Inquiry, saying *“Some patients had heard that HCV screening tests had been implemented in other countries and they may have felt that the UK blood services were not quick enough in introducing HCV testing which could put them at risk. I thought this might result in patients who receive a lot of donations such as people with haemophilia, possibly taking legal action.”* However, she was supportive of the coordinated national start date. Written Statement of Dr Jean Harrison paras 512-515 WITN7046001

963 Letter from Professor Allain to Dr Harrison 1 July 1991 NHBT0000075\_004. Of note is that at an East Anglia Blood Transfusion Centre meeting on 8 April 1991, Professor Allain himself said he would prefer to introduce routine testing at an early date and *“The National Directorate would be informed that Cambridge would commence routine testing as soon as possible and would not necessarily await the outcome of the test kit evaluation.”* Notes on Management Group meeting 8 April 1991 p2 NHBT0041282\_003. By a further meeting on 20 May 1991, funding had been agreed and a commencement of July was likely. Minutes of Executive meeting 20 May 1991 p2 NHBT0041278. In the event, the Cambridge RTC officially started testing on the nationally coordinated date of 1 September 1991. Written Statement of Dr Lorna Williamson para 492 WITN0643010. Professor Allain recollected starting on 1 August 1991 to ensure that all labile blood products were already tested at the official starting date. Written Statement of Professor Jean-Pierre Allain para 190 WITN3599001

964 Letter from Dr Harrison to Professor Allain 2 July 1991 NHBT0000075\_007

## Introduction of testing

On 30 July 1991, John Canavan wrote for the attention of Baroness Hooper recommending that a “*low key announcement*” be released to mark the introduction of anti-HCV testing. He noted that “*there may ... be questions about why testing was not introduced earlier as it was in some other countries.*”<sup>965</sup> A press release was duly issued on 16 August 1991, quoting Baroness Hooper as saying:

*“We are fully committed to ensuring that patients in our hospitals receive safe blood transfusions. To achieve this every blood donation already undergoes a series of tests before it is used.*

*We are now satisfied that donations can also be screened for Hepatitis C using tests which have been developed recently. The introduction of this additional test will further improve the safety of our blood supply and we can counsel donors in appropriate cases about their own health.”*<sup>966</sup>

The UK commenced routine anti-HCV screening on 1 September 1991, using Ortho, Abbott and UBI ELISA tests with confirmatory testing using RIBA II tests in reference laboratories.<sup>967</sup> Professor Tedder raised a concern on 4 September 1991 that ELISA-positive but RIBA-negative samples might contain the virus.<sup>968</sup> As a result, Dr Gunson advised all RTC directors that no blood products should be issued from repeatedly ELISA-positive donations.<sup>969</sup>

At the time, Dr Gunson and others were working on a journal article reporting on the pilot study.<sup>970</sup> Dr Rejman wrote to Dr Gunson on 11 September 1991, requesting amendments to the draft article to mitigate or forestall potential criticism regarding the timeline for introducing screening, including “*an indication of the delay due to lack of supplementary testing.*”<sup>971</sup> However, Dr Gunson replied that he did not “*think we should attempt in a scientific article to try to justify any alleged delayed introduction of anti-HCV screening.*” He did not think any delay was caused by RIBA II not being available, but said that, “*There was a delay between the two phases of the study but this was caused by the sheer logistics of transferring samples from three RTCs to each of their confirmatory laboratories and the fact that 65 PCRs took a long time to complete.*”<sup>972</sup>

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965 Memo from John Canavan to Mary Delfgou 30 July 1991 NHBT0000192\_125. The sense that the Department of Health might be vulnerable to complaints about the delay in introducing testing is clear, and needs to be borne in mind in considering whether the later disappearance from official files of documents relating to the decisions of the ACVSB was deliberately selective: see the chapter on *Document Destruction*.

966 Department of Health press release *Minister Announces Additional Testing of Blood Donations* 16 August 1991 NHBT0000062\_098

967 Letter from Violet Rawlinson to all RTC directors 1 March 1992 p1 SBTS0000665\_091

968 Letter from Professor Tedder to Dr Gunson 4 September 1991 NHBT0006341

969 Letter from Dr Gunson to all RTC directors in England and Wales 11 September 1991 NHBT0000193\_025

970 Draft paper, intended for submission to *Vox Sanguinis: Hepatitis C Viraemia in UK Blood Donors: A Multicentre Study* 30 August 1991 pp2-20 WITN4486065

971 Letter from Dr Rejman to Dr Gunson 11 September 1991 p2 NHBT0000015\_117

972 Letter from Dr Gunson to Dr Rejman 16 September 1991 NHBT0000015\_119

On 15 November 1991, Baroness Hooper wrote to Sir Robert McCrindle MP in connection with a letter he had received from a constituent about Hepatitis C testing:

*“The decision on whether and when to introduce any new screening test for blood donors is almost invariably a complex one and the Department has to strike a balance between the benefit to recipients, the amount of potential waste of good quality donations and the costs involved. The Department has various committees of internationally recognised experts to advise on the best way forward. On the basis of their advice, routine screening was not introduced immediately when the first unsatisfactory version of the screening tests were available, but only when better and additional tests made it appropriate to do so.*

*The cost benefit of the screening was also considered in greater detail that could be given in the article enclosed with your letter, which drew together all the cost benefit factors. You will appreciate that in the health field the benefits derived from specific medical interventions cannot be assessed very easily and judgements have to be made on the best available evidence.”*<sup>973</sup>

On 5 March 1992, Dr Gunson and Violet Rawlinson produced a report regarding the first months of anti-HCV testing. Overall, 0.39% of donations were repeat positives (down from an anticipated 0.5%, as predicted by trials before routine screening commenced).<sup>974</sup>

## Commentary

There can realistically be little dispute about the fact that Hepatitis C screening was urgent. The consequences of infection being transmitted by blood had been recognised as a real risk since 1979. Whatever uncertainties remained about quite how serious infection was, and how widespread the more severe consequences of cirrhosis and liver cancer were, planning needed to assume that these risks were well-founded and should be taken seriously. By 1985, Professor Zuckerman spoke of a specific test for non-A non-B Hepatitis being “*awaited with breathless anticipation*”, thereby conveying both the importance of developing such a test and the urgency of doing so.<sup>975</sup> At its second meeting (and the first at which it considered the question of Hepatitis C testing) the ACVSB recorded that testing was regarded as “*a priority*.”<sup>976</sup>

Consideration of the decision-making process that then followed, however, as described above, indicates that it was not in fact treated as the priority that it should have been.

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973 Letter from Baroness Hooper to Sir Robert McCrindle 15 November 1991 DHSC0003565\_079. Baroness Hooper thanked Sir Robert McCrindle for passing on correspondence received from his constituent which he had also passed on to the Minister of State for Health, Virginia Bottomley. Letter from George Hart to Sir Robert McCrindle 10 October 1991 DHSC0002500\_107, Letter from Sir Robert McCrindle to Virginia Bottomley 16 October 1991 DHSC0014989\_156

974 Anti-HCV Tests on Blood Donations in the UK 5 March 1992 pp3-4 NHBT0027699\_005

975 *A and Others v National Blood Authority* Judgment 26 March 2001 para 158(i) PRSE0003333, Zuckerman *Is the Enigma of Non-A, Non-B Hepatitis being Solved?* Journal of Hepatology 1985 p3 NHBT0082922

976 Minutes of ACVSB meeting 22 May 1989 p3 NHBT0005019



By October 1989 it was, or should have been, apparent that there was a reasonably effective test. As Mr Justice Burton (correctly) pointed out in *A and Others v National Blood Authority* the Ortho assay was published in *Science* in April 1989 and had been evaluated internationally from that date onwards. Dr Alter concluded that “*the discovery of [Hepatitis C] is a fundamental breakthrough in virology*” and went on to urge that it should immediately be implemented for donor screening once licensed.<sup>977</sup> Dr Barbara went to the Paris meeting in June 1989 regarding the test as “*reproducible, robust and meaningful*”; Dr Mortimer reported that “*he considered the findings represented a persuasive case that the Chiron test results were reliable*.”<sup>978</sup> Dr Gunson came away from Rome in September with a “*positive reaction*”, although he was worried about specificity, and thus false positives, in the absence of a confirmatory test.<sup>979</sup> He was quoted in *The Independent* saying “*the consensus in Rome was that it represented a significant breakthrough*.”<sup>980</sup>

As Dr Gunson put it in his letter of 2 October to Graham Hart: “*There is no doubt that this test is detecting a virus which causes transfusion transmitted NANBH*.”<sup>981</sup>

It is not surprising that John Canavan, writing internally in early October, considered that the ACVSB might recommend the introduction of routine screening at its next meeting.<sup>982</sup>

Dr Metters, however, was more reticent, recording that “*we have no idea of the false positive or negative rate*.”<sup>983</sup> Dr Perry (a member of the ACVSB) recalled a reluctance on the part of Dr Metters, a concern that all the details had to be got right before the bigger “in principle” decision could be made.<sup>984</sup> This is reflected in the discussion at the ACVSB’s meeting on 6 November 1989, where Dr Metters expressed the need for “*more facts and figures*” and, instead of recommending the introduction of routine screening, the ACVSB decided that it needed to know “*a great deal more*” about the test, required a confirmatory test and “*would not want to go on in advance of an FDA decision*.”<sup>985</sup>

Notwithstanding this desire for more data before making what may have seemed a likely decision, the meeting – expressly one where the “main issue” was whether the time was

977 *A and Others v National Blood Authority* Judgment 26 March 2001 para 158(ii) PRSE0003333, Kuo et al *An Assay for Circulating Antibodies to a Major Etiologic Virus of Human Non-A, Non-B Hepatitis* *Science* 21 April 1989 pp4-6 BAYP0000012\_094, Alter *Discovery of the Non-A, Non-B Hepatitis Virus: The End of the Beginning or the Beginning of the End* *Transfusion Medicine Reviews* April 1989 p4 NHBT0083811

978 *A and Others v National Blood Authority* Judgment 26 March 2001 paras 147, 158(iii) PRSE0003333, HCV Assay Preliminary Report No2 23 June 1989 p4 NHBT0000017\_006, *A and Others v National Blood Authority* Transcript 30 October 2000 pp139-140 NHBT0086759\_001, *A and Others v National Blood Authority* Transcript 31 October 2000 p91 NHBT0000151\_001, Minutes of ACVSB meeting 3 July 1989 p2 NHBT0000072\_025

979 *A and Others v National Blood Authority* Judgment 26 March 2001 para 158(iii) PRSE0003333

980 *The Independent Blood may be tested for Hepatitis C virus* 22 September 1989 NHBT0000061\_049

981 Letter from Dr Gunson to Graham Hart 2 October 1989 p2 NHBT0000188\_056

982 Memo from John Canavan to Jane Wheeler NHBT0000188\_062

983 Memo from Dr Metters to Graham Hart 9 October 1989 NHBT0000188\_074

984 Dr Robert Perry Transcript 1 April 2022 pp149-150 INQY1000202, Dr Robert Perry and Dr Brian McClelland Penrose Inquiry Transcript 23 November 2011 p50 PRSE0006068

985 Minutes of ACVSB meeting 6 November 1989 pp4-5 NHBT0005043



right for adopting the Chiron test – did take a decision to support the general introduction of the Chiron test provided two requirements were fulfilled: (1) if the FDA approved it; and (2) pilot tests showed it to be feasible and non-problematic.<sup>986</sup>

The first of these two preconditions was understandable when the UK was not itself in a position to carry out a scientific evaluation of the test – but that was remedied in December when the US authorities granted an export licence. The significance of this is that the UK no longer needed to depend on the country of origin licensing the test. Nothing prevented it then from conducting its own scientific evaluation with a view to adopting it if satisfactory.

The second precondition was also satisfied by 18 December 1989 and confirmed in January 1990 when Dr Gunson presented the results of pilot tests.<sup>987</sup>

A third issue had been raised at the 6 November meeting: the need for confirmatory testing. As to this, Dr Gunson also advised on 4 January 1990 that the ACVSB did not see the absence of a confirmatory test as a barrier to the introduction of routine screening, but that it would insist that any routine test be licensed by the FDA. It was in any event known that a confirmatory test was under development and was thus to be expected soon.<sup>988</sup>

There seems little good reason why a test should not have followed within a short period. The basic requirements before a test could be implemented<sup>989</sup> were the carrying out of pilot studies and evaluations (which had largely been completed by the start of 1990), planning for counselling and implementation (which if it had not been, should have been foreseen and addressed in advance, anticipating what was a racing certainty by mid 1989 that the long-awaited test for Hepatitis C was about to be introduced<sup>990</sup>) and the execution of that implementation in respect of equipment, staff and building works. Parts of the UK might have needed longer than others to achieve this, but it should have been reasonably achievable within three months. Moreover, for the reasons expressed above when discussing the response to Dr Lloyd, it was not necessary for best protection of the health of those receiving transfusions that all should have to wait until every RTC was in a position to introduce screening on the same date.

At this and its later meetings, the ACVSB's focus became the obtaining of more, and better, data, rather than a focus upon the public health implications of not introducing routine screening. Dr Perry, in giving evidence both to the Penrose Inquiry and to this Inquiry, thought that the composition of the ACVSB was unduly biased to virology and that "*the public health*

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986 Minutes of ACVSB meeting 6 November 1989 p5 NHBT0005043

987 Minutes of NBTS HQ meeting 18 December 1989 NHBT0000188\_136, Pilot Trial of Anti-HCV Tests on Blood Donations 10 January 1990 NHBT0000061\_095

988 Minutes of National Directorate of NBTS National Management Committee meeting 4 January 1990 pp4-5 NHBT0071870\_002

989 Mr Justice Burton identified these at paragraph 170, and I am satisfied did so appropriately and correctly. *A and Others v National Blood Authority* Judgment 26 March 2001 PRSE0003333

990 Mr Justice Burton recorded that "*Dr Gunson accepted that, in retrospect, the fact that no preplanning was done for a year was obviously not satisfactory. Had there been counselling procedures in place, it appears to me that the system might have been able to cope, albeit with difficulty, as the West Midlands Report had indicated in December 1989, even without the confirmatory test*". *A and Others v National Blood Authority* Judgment 26 March 2001 para 165(i) PRSE0003333

*perspective was not as dominant ... as it possibly could have been.*" His observation was that *"the best became an enemy of the good"* and that the search was for *"perfect outcomes rather than good outcomes that could meet a public health need."*<sup>991</sup> I agree.

It is clear that concerns regarding false positives, and the efforts that would be involved in counselling donors, preoccupied a number of those involved in decision-making and led to the decision to await the availability of a confirmatory test. However, a decision not to test in order to avoid causing worry and distress to affected donors overlooked the importance of catching the true positives, both to prevent infected blood being used for transfusion recipients, and to properly inform donors of their own health status and risks of community transmission.

It may justifiably be said, considering the position as at the beginning of 1990 and thereafter, that the ACVSB and the Department of Health were not approaching the question of anti-HCV testing with a sufficient sense of urgency when considering from a public health perspective the Hepatitis C infections that could be prevented and the lives that could be saved.

It is unclear why it was regarded as so important to await the licensing of the Ortho test by the FDA, given that, even once the FDA had granted a licence, screening was still not introduced.<sup>992</sup>

The decision in 1990 to delay the start of screening because two second-generation tests were now available, and a decision needed to be made which was preferable, was indefensible. The underlying assumption was that a test was needed. There can be no argument with the idea that it ought to be the best available test. However, there was no good reason why a decision as to whether it was better to use a second-generation test, and if so which, should delay a currently available and acceptable test starting to be used. Evaluation of the second-generation test could take place contemporaneously: it did not need to be and should not have been done sequentially. Further delay was hinted at when two further tests, Organon Teknika and UBI, came into view. There was no good reason for this.

Though during the hearing of *A and Others v National Blood Authority* in front of Mr Justice Burton, leading counsel for the National Blood Authority expressly accepted in relation to surrogate screening that cost should not be a determining factor, and did not suggest that it should be a factor in considering routine screening (indeed, it would

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991 Dr Robert Perry and Dr Brian McClelland Penrose Inquiry Transcript 23 November 2011 pp136-137 PRSE0006068, Dr Robert Perry Transcript 1 April 2022 pp137-139 INQY1000202

992 Mr Justice Burton concluded as to this that *"If in fact a delay until May 1990 was simply in order to rely on evaluation by the United States, notwithstanding the fact that the Export Licence had been issued on the basis that the United Kingdom would be able to do its own evaluation, then, particularly given the priority to which I have referred, I can see no reason why such evaluation should not have been done; and Dr Gunson confirmed that the Department may well have been satisfied not to wait until FDA licence if suitable testing had been done by the UK. The opportunity was there for such UK tests to be done, by virtue of the early knowledge of the assay referred to in paragraph 147 above, and the limited evaluation that was done by Drs Contreras and Barbara, referred to in paragraph 148 above; and Dr Gunson accepted that some countries did commence testing before FDA approval, having carried out their own trials."* *A and Others v National Blood Authority* Judgment 26 March 2001 para 162(iii) PRSE0003333. It is difficult to disagree with any of this, and I do not do so.

be inconsistent to adopt such a position unless the costs of direct screening were of a different order of magnitude from those involved in universal surrogate screening; no such suggestion was made),<sup>993</sup> it is difficult to avoid the fact that at times throughout the account set out above there was concern about the funding implications of testing, even to the extent that a minute from Mark Fuller said that delay “*can only help*”.<sup>994</sup>

As country after country introduced screening, the UK’s position became increasingly indefensible. Dr Lloyd was right in his expression of concern (to Dr Gunson) that the UK had fallen behind many other developed countries: the UK should, he said, be “*at the forefront, not just trailing along at the end*.”<sup>995</sup>

Mr Justice Burton provided a timetable of when other countries commenced screening for Hepatitis C:

Month <sup>996</sup>	Countries
November 1989	Japan
February 1990	Australia
March 1990	France (1 March), Luxembourg (new donors only, 1 March)
April 1990	Finland (1 April - all donations; partially started 1 February)
May 1990	US (2 May), Austria, Amsterdam (other Netherlands centres later)
June 1990	Canada, Germany (by 1 July)
July 1990	Belgium (1 July)
August 1990	Switzerland (1 July)
September 1990	Luxembourg (all donors)
October 1990	Italy (many centres), Spain (all by 12 October, some started earlier)
1990/91	Norway
January 1991	Sweden (legal requirement published 24 January to start as soon as possible)

993 *A and Others v National Blood Authority* Judgment 26 March 2001 para 120, para 169 PRSE0003333. The “*sixth and last factor*” raised by counsel for the National Blood Authority against a case that universal screening should have been introduced earlier than 1 April 1991 (that date was conceded by the NBA towards the start of the trial) was “*Funding and Decision-Making*”. This was an argument that it necessarily took time to decide to make provision for the necessary funding rather than that it “cost too much”. It was met by the judge’s view that arrangements to provide it could have been made earlier. I agree.

994 Memo from Mark Fuller to Eric Evans 4 February 1991 p2 NHBT0000062\_026

995 Letter from Dr Lloyd to Dr Gunson 24 June 1991 NHBT0000076\_009

996 *A and Others v National Blood Authority* Judgment 26 March 2001 para 143 PRSE0003333. See also Counsel Presentation on the International Understanding of, and Response to, Risk of Hepatitis and HIV/AIDS January 2023 pp143-151 INQY0000439

Month <sup>996</sup>	Countries
March 1991	Portugal (mandatory, some earlier), Cyprus, Greece, Hungary, Iceland, Malta (all 'not before' March)
April 1991	Netherlands (mandatory 1 April)
June 1991	Denmark
August 1991	Italy (balance)
September 1991	UK (1 September)
September/October 1991	Ireland

When, in July 1990, the ACVSB came down in favour of Hepatitis C screening (in effect, again, given that the preconditions from its November 1989 meeting had each been addressed satisfactorily to the independent observer) it failed to recommend that testing be commenced immediately (or to give any date for its introduction). Instead it advised that there should first be a yet further study, this time evaluating the Ortho and Abbott tests to determine which was more suitable.<sup>997</sup> This was a wholly inadequate approach to the known risk of avoidable harm, and death, to transfusion recipients of blood not tested for anti-HCV. The assessment of the relative merits of the two tests could and should have been undertaken concurrently with the implementation of the screening.<sup>998</sup>

Over four and a half months then elapsed before the ACVSB met again. When it did so, it concluded that it was important to start screening “*as soon as practicable*” but failed again to specify any particular date by which such screening should be in place. Instead it was decided that there should be consultation on a start date with regional transfusion directors, but Dr Gunson was asked to hold off until a submission had been put to ministers.<sup>999</sup> It took a further month for a submission to be sent, and it was not until 16 January 1991 that ministerial approval was given.<sup>1000</sup>

Thereafter, the decision to evaluate the second-generation tests rather than proceed immediately with the introduction of screening was wholly unjustifiable: there was no good reason why such evaluation could not have proceeded concurrently with the introduction of testing.

Two further features of the decision-making process call out for comment. One was the secrecy of decision-making: it was, said Dr Perry, forcefully underlined by the Deputy Chief Medical Officer chairing the ACVSB that what was being discussed had to be kept

997 Minutes of ACVSB meeting 2 July 1990 p3 PRSE0000976

998 John Canavan’s written evidence was that he did not recall the suggestion being made, and it would have raised “*significant operational considerations for the RTCs, in terms of staffing, equipment and donor counselling arrangements.*” Written Statement of John Canavan para 2.107 WITN7115001

999 Minutes of ACVSB meeting 21 November 1990 p4 NHBT0000073\_018

1000 Memo from John Canavan to Dr Smales and others 21 December 1990 PRSE0004667, Memo from Mary Delfgou to John Canavan 16 January 1991 NHBT0000191\_013

“*absolutely confidential and secret*”.<sup>1001</sup> A problem with such confidentiality was that those outside the membership of the ACVSB (and those “in the know” in the Department of Health and the other health departments), who might have a great deal of informed opinion and expertise to bear, were not in a position to influence or inform decision-making. There was thus no scope for constructive criticism of the ACVSB’s approach: no opportunity for those who might be approaching matters from a public health focus to raise concerns about the quest for “*perfect outcomes*”.<sup>1002</sup>

The second was the relatively limited information provided to ministers and the corresponding lack of any ministerial steer or impetus or challenge. The responsible minister was Baroness Hooper, who had been appointed Parliamentary Under-Secretary of State in October 1989. Baroness Hooper, as she told the Inquiry, had no health background or experience; in common with many other ministers, it was “*in at the deep end*”.<sup>1003</sup> She would thus have been heavily reliant on information and advice from civil servants.<sup>1004</sup> Minutes of the ACVSB’s decisions were not published, and were not shared with ministers.<sup>1005</sup> The custom was to give ministers “*the consensus view*” rather than flagging up any differences of advice or opinion within the committee.<sup>1006</sup>

The first submission to the Minister on this issue was February 1990. It provided little by way of background, mentioned nothing about the seriousness of Hepatitis C, and merely informed the Minister of the ACVSB’s decision that there was “*still insufficient scientific information about the test to advise its routine introduction.*”<sup>1007</sup> Nothing was spelt out about the implications of not introducing testing at that stage, and no reference was made to the different view that had been expressed by Dr Mortimer at the ACVSB’s January 1990 meeting. Nor was any reference made to the position in other countries. The Minister was not asked to make any decision at this stage as to what the policy should be.

The second submission – like the first, little more than a short note – to the Minister was in May 1990, informing her of the ACVSB’s view that the introduction of routine screening would not yet be justified.<sup>1008</sup> It did not alert her to the fact that a precondition set the previous November had been satisfied now that the FDA had licensed the test; nor that the test had proved practicable in RTCs; nor that the one other concern, confirmatory testing, was well on the way to being resolved and in the eyes of Dr Gunson should not hold matters up. Again no decision was sought and nothing was said about the implications of doing nothing, although the fact that screening had recently been introduced in some European countries was recorded.

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1001 Dr Robert Perry Transcript 1 April 2022 pp140-141 INQY1000202

1002 Dr Robert Perry Transcript 1 April 2022 p138 INQY1000202

1003 Baroness Gloria Hooper Transcript 30 June 2022 p8, p10 INQY1000218

1004 Baroness Gloria Hooper Transcript 30 June 2022 p74 INQY1000218

1005 Baroness Gloria Hooper Transcript 30 June 2022 pp61-62 INQY1000218

1006 Baroness Gloria Hooper Transcript 30 June 2022 p84 INQY1000218

1007 Memo from Pam Reenay to Dr Metters and Private Secretary to the Parliamentary Under-Secretary of State in the Lords 15 February 1990 NHBT0000189\_055

1008 Memo from John Canavan to Dr Metters and Elizabeth Baldock May 1990 NHBT0000061\_130



After the ACVSB's July 1990 meeting, a further minute was sent to the Minister – over a month after the meeting. This informed her that the ACVSB had advised “*in principle*” that all blood donations should be screened for Hepatitis C, and that a full submission setting out the case for screening, the financial implications and results of a cost benefit study would be provided “*shortly*”.<sup>1009</sup> The Minister was not told that FDA approval had been given for the test, nor that testing had commenced in the US. Again no decision was sought from her.

No further submission was provided to her “*shortly*” thereafter. The ACVSB did not meet again until 21 November 1990, with a detailed submission being sent (on this occasion) to the Minister on 21 December with advice from the Chief Medical Officer on 31 December.<sup>1010</sup> This was the first time that the Minister was asked positively for a decision, and she gave her approval on 16 January 1991.<sup>1011</sup>

This submission informed the Minister that it was unlikely that routine screening could be introduced before 1 April 1991. In fact, as detailed above, the date of introduction slipped, from April to July to September: this was not an issue flagged up to the Minister, who was told only about Newcastle starting screening in advance of the rest of the UK.<sup>1012</sup>

It is disappointing that so little information was provided to the Minister before December 1990: if “advisers advise and ministers decide”, ministers need to be given sufficient information to probe, to challenge, to ask questions, to seek more information. Equally ministers must be alert to the importance of subjecting the advice they receive to scrutiny and asking for further information when appropriate. Given that there had been press interest in this issue, and a number of Parliamentary questions raised,<sup>1013</sup> and in light of the fact the transmission of HIV by blood and blood products had taken place, with such devastating effects, only a few years previously, it is surprising that there was no ministerial curiosity or intervention regarding this issue, either from the responsible minister or from the Secretary of State for Health – Kenneth Clarke until November 1990, and thereafter William Waldegrave.<sup>1014</sup>

In his evidence to the Inquiry Dr Perry identified a number of shortcomings in the decision-making process with regard to the introduction of routine testing.<sup>1015</sup> These included:

- (a) Unnecessary secrecy and confidentiality.
- (b) A late recommendation in principle for the introduction of testing, driven primarily by scientific rigour rather than urgent public health considerations.

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1009 Memo from John Canavan to Elizabeth Baldock 7 August 1990 NHBT0000061\_169

1010 Memo from John Canavan to Dr Smales and others 21 December 1990 p4 PRSE0004667, Memo from John Canavan to Dr Smales 21 December 1990 DHSC0002498\_096

1011 Memo from Mary Delfgou to John Canavan 16 January 1991 NHBT0000191\_013

1012 Memo from Dr Rejman to Baroness Hooper 30 April 1991 NHBT0000062\_053

1013 Memo from Pam Reenay to Dr Metters and Private Secretary to the Parliamentary Under-Secretary of State in the Lords NHBT0000189\_055

1014 It should be noted that William Waldegrave took up the position of Secretary of State for Health on 2 November 1990, which was, in fairness, less than three months before Baroness Hooper gave her approval on 16 January 1991.

1015 Written Statement of Dr Robert Perry WITN6920001 para 458, Dr Robert Perry Transcript 1 April 2022 pp151-153 INQY1000202

- (c) The absence of a clear plan, timescale, strategy or policy guidance from the Department of Health or the SHHD for the introduction of testing following the in principle recommendation in July 1990.
- (d) The progressive and largely unexplained deferral of the UK start date from April to July to September 1991.

Each of these criticisms is well-founded. I agree with them and would add that these are not matters that are discernible only with hindsight.

Dr Perry also acknowledged a failure on the part of SNBTS to argue robustly the case for the earlier introduction of testing in Scotland with the SHHD or Scottish ministers, including pointing out the public health consequences of delays; and suggested that there was a reluctance on the part of SHHD to consider such an option, preferring to be guided by timescales determined by the Department of Health:

*“I think the problem in Scotland arose when I think colleagues in Scotland felt that this process was being delayed over and over again for no good reason for us in Scotland because all the systems are in place, the funding was in place, the expertise was there, the counselling algorithms for the donors was all in place, and there was very serious concern expressed by the then general manager, Mr Mackintosh, that actually we should be implementing this ... But I think SHHD came back and said no, this is a UK-wide decision.”*<sup>1016</sup>

It was reasonable for the SHHD to take the position initially that the decision to commence routine testing would be made simultaneously throughout the UK. But the SHHD did not shift from this stance, even when it was, or should have been, apparent to it that the decision-making was taking far too long. It did not give proper consideration to the option of going ahead with screening in Scotland.<sup>1017</sup>

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1016 Dr Perry Transcript 1 April 2022 p147 INQY1000202

1017 In January 1989 Dr McIntyre (SHHD) wrote to Dr Pickles (Department of Health) explaining that *“In Scotland we are under considerable pressure from the SNBTS to fund the introduction of additional virological testing and as this is a matter which we feel should be addressed on a UK basis, I should be grateful if you could let me know what steps your Department intends to take in this matter as we would not like to be forced into a course of action which might have repercussions for the UK as a whole.”* Letter from Dr McIntyre to Dr Pickles 9 January 1989 PRSE0001884. The Secretary of State for Scotland wrote to Roger Freeman, the Parliamentary Under-Secretary of State for Health, in February 1989 with regard to the formation of the ACVSB, setting out his view that it was *“important that the UK Blood Transfusion Services should act in unison on this subject.”* Letter from Michael Forsyth to Roger Freeman 8 February 1989 PRSE0000967

In August 1989 George Tucker of the SHHD briefed the Secretary of State for Scotland on the position as at that date, explaining that the ACVSB would be discussing the test at their next regular meeting. The “line to take” for the Secretary of State included *“UK blood is still considered one of the safest in the world, and we continue to investigate ways of making it safer still”* and *“The prevalence of HPC [Hepatitis C] in the population in this country has not been established, nor has the role of blood in its transmission.”* George Tucker advised that this was *“a UK issue and D of H [Department of Health] will be taking the lead but SHHD and SNBTS will be represented in any meeting and the Minister will be consulted before any decisions are taken.”* Memo from George Tucker to Secretary of State and others 23 August 1989 PRSE0000558

Dr McIntyre’s perception, as at June 1990, in a minute to Scotland’s Deputy Chief Medical Officer Dr Young, was that *“Things are moving very fast on the Hepatitis C front”* and he anticipated that

Responsibility for the failure to ensure the timely introduction of Hepatitis C screening lies primarily with the Department of Health, which was regarded as very much in the lead on this issue. However, it is a responsibility shared with the SHHD, in the respect identified above, and with the blood services more generally for their failure to push for the earlier introduction of testing.

## Concluding words

This chapter began by asking whether, at the end of a detailed account of what happened, a reader would see the same themes of repeated delay, decision-making “going round in circles”, a desire for perfection in detail preventing measures which were “merely good” from being introduced, an unnecessary desire to have available the fullest information from the best studies available before taking any decision, and the same culture of decision-making and approach<sup>1018</sup> in the case of whether and when to introduce a direct test for Hepatitis C as there had been in relation to whether and when to introduce a surrogate test.

The answer given by everyone who has read the detail will almost certainly be: “Yes”.

There remains one issue to discuss. When, reasonably, should screening have started?

## Date at which screening should reasonably have begun

For the reasons he expressed in his judgment in *A and Others v National Blood Authority*, Mr Justice Burton concluded that universal screening should have been adopted by March 1990. He had the advantage of hearing from Dr Gunson, whose role as the consultant adviser to the CMO on matters of blood transfusion was pivotal. This Inquiry has undoubtedly seen more documentation and heard more evidence than he did, and has a wider context into which to place the evidence he heard.

Blood safety should have been prioritised. There was no credible evidence to show that safety would or might be compromised by introduction of the Chiron test in early 1990. Although there was room for scientific debate about the extent to which the test accurately identified all cases of infection, there was in practical terms little doubt that it identified many. Introducing it would have saved many infections, much cirrhosis, and undoubtedly some early deaths. The UK would not have been the first nation to have introduced Hepatitis C screening had it done so in the first three months of 1990. Although all centres were screening before the end of March 1990, some centres (especially those which had already performed

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at the next ACVSB meeting it would be decided that “*there is no alternative but to recommend the introduction of the test.*” He suggested delaying further action until the ACVSB meeting on 2 July. Memo from Dr McIntyre to Dr Young 6 June 1990 PRSE0003099. The account of what happened at and following the 2 July 1990 meeting has been set out in this chapter: it cannot be said that “*moving very fast*” was an accurate description of the actions of any of the bodies involved in consideration of the introduction of routine testing.

1018 There was a failure to adopt a structured approach to decision-making, which would have involved recognising any paramount principle (eg patient safety) and then ensuring that other considerations were seen in that context when evaluating the facts. Instead of starting with the overriding purpose of the decision, there was a paralysis of decision-making.

pilot schemes) could have done so earlier and should have done so as soon as they were ready. There was no need to wait for FDA licensing; the UK had not done so with the test used for HIV, and could have evaluated for itself. There was no need to wait to see which of two tests was preferable when each could have done the task required; improvements could have been made whilst testing was in progress, as had been done with Hepatitis B. I agree with Mr Justice Burton in his choice of a date by which screening should have started.

The last word, save one, should go in this chapter to Dr Gunson in evidence highlighted by Mr Justice Burton, where he said in concluding this part of his decision:

*“I have already referred to Dr Gunson’s evidence, subject to the question of a confirmatory assay as to ‘certainly early in 1990’, in retrospect. Later in cross-examination, he said ...*

*‘ ... I have now said three times – I think I did say to His Lordship yesterday – that in retrospect we should have done it a different way.’”<sup>1019</sup>*

The one further matter is that it follows from the chapter on *Hepatitis C Surrogate Screening*, and this one on direct screening, that surrogate testing should have begun earlier in the 1980s (and no later than 1986), with a view to identifying as many cases of NANBH/ Hepatitis C that could be identified and preventing their transmission through the blood; and that should have been in place until, by March 1990, it should have been superseded by universal Hepatitis C screening, to be improved and refined over the years that followed.

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1019 *A and Others v National Blood Authority* Judgment 26 March 2001 para 171 PRSE0003333. Mr Justice Burton added “[The QC for the National Blood Authority] *of course, points out ... that the use of hindsight is dangerous, and very often introduces too stringent a test. But my task, on [this] case, examining all the **circumstances**, is to conclude, looking back on the full picture, what the public was entitled to expect, and I conclude that in fact, Dr Gunson, a supremely fair man, is in fact looking back with my spectacles.*” Like Mr Justice Burton I am not concerned with whether there was civil liability for negligence: I cannot be, since the Inquiries Act 2005 prohibits it. But I am concerned with whether the decision that was made is open to criticism and to conclude what should have been done, and it seems to me that this comment was and is fully justified.

## 5.6 HIV Lookback

This chapter examines the UK's HIV lookback schemes and their effectiveness. It considers the steps taken to employ lookbacks both before and after the introduction of screening for HIV, practices in different geographic areas and the effectiveness of the UK's HIV lookback schemes as a whole.

### Key dates

**October 1984** blood donor diagnosed with AIDS at Bournemouth Hospital.

**20 December 1984** CMO confirms publicly that recipients of the donations made by the blood donor who had AIDS have been traced.

**10 July 1985** regional transfusion directors agree that the blood services will make the initial approach to a donor where a positive donation is found.

**1 October 1985** EAGA meeting: Dr Contreras says AIDS patients should be asked if they have donated blood in the last five years.

**14 October 1985** blood in the UK begins to be screened for HIV and a five year lookback programme is introduced.

**26 November 1985** EAGA meeting: Dr Tedder asks members to consider asking seropositive patients if they have donated blood since 1978.

**15 January 1986** EAGA meeting: Dr Contreras asks again that clinicians routinely ask patients with HTLV-3 antibodies or AIDS if they have donated blood.

**23 April 1986** CMO's Dear Doctor letter asks clinicians to ask whether HTLV-3 patients ever donated blood.

**September 1990** PHLS report examines lookbacks from 1985 to 1989 and finds differences of practice and gaps in records.

### People

**Dr Marcela Contreras** deputy director, North London Blood Transfusion Centre

**Dr Harold Gunson** director, NBTS

**Dr Patricia Hewitt** consultant haematologist, North London Blood Transfusion Centre

**Dr Tim Wallington** consultant immunologist, Bristol Regional Transfusion Centre

### Abbreviations

**CDSC** Communicable Disease Surveillance Centre

**EAGA** Expert Advisory Group on AIDS

**NLBTC** North London Blood Transfusion Centre



## Introduction

Tracing recipients of infected blood and identifying the donors who donated blood received by infected recipients is fundamental to preventing the onward spread of HIV and, where possible, to provide a patient with treatment.<sup>1020</sup> Where a disease threatens, but is not so widespread as to be incapable of containment, “trace and track” can confine its spread. This chapter examines the UK’s HIV lookback and how effective it was.

Themes that run through the chapter include questions of the speed of response; whether those who had given donations of blood which were probably infected should be told; whether those who received possibly infected donations should be told; in either case who should be responsible for telling them; and whether (and in what form) counselling should be made available to those donors or recipients who were identified as probably being infected. Another theme is the difficulty in England (in particular) of managing a coordinated response, for reasons including confidentiality, ethics, finance, and the excessive demands on time that poor record keeping in particular caused.

A phrase first used in 1986,<sup>1021</sup> “lookback” means identifying patients who were given blood from donors who were later shown to be infected with a blood-borne virus. Broadly, there were two different types of HIV lookback:

- (a) A reverse lookback is where a patient presents with signs and symptoms of AIDS and an investigation is undertaken to identify whether the patient received blood or blood products, and if so from whom. Reverse lookbacks had been undertaken in the UK since the 1940s in the context of transfusion-transmitted hepatitis and Hepatitis B.<sup>1022</sup>
- (b) A targeted lookback is where an infected blood donation is identified and recipients are traced to see whether or not they have been infected.

The distinction can be expressed as “coming from whom?” (reverse lookbacks – starting from the position of the recipient) or “going to whom?” (starting from the position of the donor).

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1020 Written Statement of Professor Marc Turner para 79 WITN3530085

1021 See Lookback: Procedures to identify, trace and offer counselling and testing to patients who received blood components from donors subsequently found to be positive in tests for HIV and HCV p6 PRSE0004042, which refers to Menitove *Status of recipients of blood from donors subsequently found to have antibody to HIV* New England Journal 23 October 1986 PRSE0000488

1022 For example, see the 1943 *Memorandum prepared by Medical Officers of the Ministry of Health* published in the *Lancet*, which describes an investigation of tracing batches of blood in the context of homologous serum jaundice and the need to ensure batch numbers “are recorded at the time of transfusion”: Homologous serum jaundice - Ministry of Health Memorandum 16 January 1943 p6 NHBT0000091\_011. See also the 1946 paper on the “*follow-up of plasma and blood transfusion with regard to the development of jaundice*” discussed in correspondence from Dr Robb-Smith at the Radcliffe Infirmary, Oxford to the Ministry of Health Extract from letter of 13 August 1946 from Dr Alistair Robb-Smith DHSC0100008\_189

Blood in the UK started to be screened for HIV from 14 October 1985<sup>1023</sup> and the HIV lookback was started upon the introduction of screening.<sup>1024</sup> The UK's HIV lookback had a five-year temporal scope: looking back to five years prior to the date the infected blood was given.<sup>1025</sup> The HIV lookback was organised centrally and began at the same time across all four nations as part of a UK-wide policy.<sup>1026</sup> However, as described below, although the HIV lookback was UK-wide it was experienced differently with some regions undertaking a large number of lookbacks, requiring significant tenacity and intensity of work, whereas other regions had fewer positive tests necessitating fewer lookbacks. Differing levels of enthusiasm and engagement amongst clinicians resulted in different degrees of success in tracing patients.

In 1985 when the HIV lookback was started there was no centralised haemovigilance system<sup>1027</sup> nor any national database recording the identity of blood donors and the recipient of the donated blood. This was despite it having been a principle of viral safety in blood that careful records should be kept, such that any donation received should be traceable to its origin. The absence of this meant that investigations tracing blood donations were time consuming and often required busy practitioners to trawl through a donor and/or patient's medical records. Those records were often poorly kept making the lookback more difficult. Moreover, there was limited input from the Department of Health and Social Security ("DHSS") or the Chief Medical Officer ("CMO") encouraging and driving forward a formal HIV lookback, which may have impacted on the priority with which it was accorded.

Once a viable anti-HTLV-3 test was available and blood throughout the UK was screened for HIV, the need for HIV lookbacks dramatically decreased. However, some individuals were infected in the "window period", that is they were given blood which was said to be free from HIV but was tested at a time between viral transfer and the development of antibodies as part of the immune response.<sup>1028</sup> Therefore, most HIV lookbacks were concentrated around 1985 but some lookbacks were required in the later 1980s and into the 1990s.

This chapter considers the lookback steps taken before and after the introduction of screening for HIV, addresses the lookbacks undertaken in different geographic areas of the UK and finally considers the effectiveness of the UK's HIV lookback.

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1023 DHSS Press Release: All blood donations now being screened for antibodies to the AIDS virus 14 October 1985 p2 NHBT0004299

1024 For a consideration of the time taken to introduce such testing, see the chapter on *HIV Screening*.

1025 Written Statement of Professor Marc Turner para 35 WITN3530085

1026 The Inquiry has been informed that the Welsh Blood Service has been unable to find any records relating to the HIV/AIDS lookback exercises and awareness campaigns in its own files and so is reliant on the documents identified by the Penrose Inquiry and those submitted to this Inquiry by others. Written Statement of Catherine O'Brien para 35 WITN6876066

1027 It was not until the late 1990s with the advent of the Serious Hazards of Transfusion ("SHOT") system and the Better Blood Initiative that such a system was established in the UK. See the chapter on *Blood Transfusion: Clinical Practice*.

1028 Dr Harold Gunson to the House of Commons Social Service Committee about an example of a donation in the window period that led to HIV infection in the recipients. Problems Associated with AIDS Minutes of Evidence 25 March 1987 p14 LDOW0000247

## HIV lookback prior to screening

Prior to the introduction of tests to screen blood for the HIV virus, the only type of lookback that could be undertaken was a reverse lookback. This depended on patients with AIDS presenting to clinicians when they were unwell, identifying that they had received a blood transfusion (or blood products) which was probably causative, and then each transfusion being traced to find the donor who might be infected. From there, other recipients of donations from the infected donor could be traced. Until the introduction of a universal screening test for HTLV-3 in October 1985 such lookbacks were reactive rather than proactive.

The HIV lookback emerged when Dr Spence Galbraith contacted Dr Harold Gunson in March 1984 about *“the problems which may arise when an AIDS patient has previously been a blood donor.”*<sup>1029</sup> In connection with their meeting on 4 April 1984, Dr Gunson replied that regional transfusion centres *“already have systems available for the follow-up of donors who are implicated in patients who develop Transfusion Associated Hepatitis”* and 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.”*<sup>1030</sup>

The meeting duly took place. A plan was made for the steps to be taken when a patient was diagnosed with AIDS and had donated or received blood or blood products. This was the first attempt at what came to be known as the HIV lookback.<sup>1031</sup>

The first step in the plan was for the appropriate regional transfusion director to be informed when a patient was diagnosed with AIDS. If the individual had donated blood that communication was to be by telephone and thereafter the steps were:

- “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 [Blood Products Laboratory] for fractionation Dr. R.S. Lane<sup>1032</sup> 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<sup>1033</sup> who will carry out any further follow-up.*

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1029 Letter from Dr Galbraith to Dr Gunson 5 March 1984 NHBT0010821\_005

1030 Letter from Dr Gunson to Dr Galbraith 3 April 1984 DHSC0006923\_071

1031 Written Statement of Dr Patricia Hewitt para 151 WITN3101006

1032 Director of BPL.

1033 Communicable Disease Surveillance Centre

*1.3.5 CDSC should be kept informed of progress.”<sup>1034</sup>*

If the diagnosed patient had themselves received blood products derived from pooled plasma involving a large number of donors, the Communicable Disease Surveillance Centre (“CDSC”) would discuss with the regional transfusion director *“the practicalities of follow-up within the resources available.”<sup>1035</sup>* Where the patient had haemophilia then Dr John Craske, Consultant Virologist at the Public Health Laboratory Service (“PHLS”), was to be involved. If the patient had received NHS blood products, Dr Richard Lane would be informed.

Where the infected individual had received products prepared and issued from the Regional Transfusion Centre (“RTC”), the action to be taken was:

*“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 [Regional Transfusion Director].*

*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.”<sup>1036</sup>*

The following week Dr Gunson reported this to a meeting of regional transfusion directors and the plan was circulated.<sup>1037</sup>

Meanwhile Dr Craske visited the Centers for Disease Control (“CDC”) in Atlanta and on his return provided an update to haemophilia centre directors that the CDC believed that the incubation period for AIDS could be as long as five years. He provided lists of batch numbers of Factor 8 used over the previous five years by two patients who were subsequently diagnosed with AIDS. Blood samples were requested from patients who had received the same batches of products.<sup>1038</sup>

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1034 Note of meeting about surveillance of AIDS in relation to Blood Transfusion 4 April 1984 p1 CBLA0001833

1035 Note of meeting about surveillance of AIDS in relation to Blood Transfusion 4 April 1984 p1 CBLA0001833

1036 Note of meeting about surveillance of AIDS in relation to Blood Transfusion 4 April 1984 CBLA0001833

1037 Minutes of Regional Transfusion Directors meeting 11 April 1984 p3 CBLA0001836

1038 Letter from Dr Craske to Haemophilia Centre Directors 16 April 1984 pp1-2 HCDO0000273\_072

An early issue which arose was what – if anything – should be said to a recipient of blood identified as potentially risky. Dr Gunson obtained the advice of the Medical Defence Union (“MDU”) which was that it was an adequate precaution that the GP should be informed “*in confidence*”. The issue was discussed at the next meeting of the regional transfusion directors on 11 July 1984. Some members doubted the MDU’s advice, based on their experience with venereal disease. It was anticipated that a DHSS working group might be set up to consider the legal implications.<sup>1039</sup>

In practice, the evidence that the Inquiry has received indicates that there was a wide variety of practices about how, whether and when people were informed – or not informed – about HIV infections from blood and blood products.<sup>1040</sup>

In late September/early October 1984 a blood donor was diagnosed with AIDS at Bournemouth Hospital, leading to a series of lookback investigations to try and find the recipients of his blood.<sup>1041</sup> Dr Donald Acheson, CMO, released a public statement on 20 December 1984 stating that the donor’s donations “*have been traced, and all possible remedial action taken.*”<sup>1042</sup> Transfusions had been given to three recipients who had tested HTLV-3 positive: a mother living in Birmingham,<sup>1043</sup> a 78-year-old man living in Wessex and a 40-year-old man from Wessex. The donor’s plasma was part of the source material for one batch of Factor 8 concentrate. 38 people with haemophilia in Wessex and South Wales had received this plasma. It was stated that “*These patients have been traced and are being monitored*”.<sup>1044</sup> Dr Patricia Hewitt notes that this was in accordance with the protocol agreed on 4 April 1984. She describes this as an example of a “*necessarily reactive rather than pro-active*” lookback in light of the fact that there was not yet at this stage “**screening, as opposed to diagnostic**” testing available.<sup>1045</sup>

At the first meeting of the Advisory Committee on the National Blood Transfusion Service (“NBTS”) Working Group on AIDS<sup>1046</sup> on 27 November 1984 it was agreed that donors should be told that their donations would be tested for HTLV-3, and that those whose donations tested positive should be informed, but there was no unanimity on how to do this. The follow up of donors and patients, counselling and contact tracing arrangements

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1039 Minutes of Regional Transfusion Directors meeting 11 July 1984 p2 DHSC0002245\_002. A subgroup of the Expert Advisory Group on AIDS (“EAGA”) would consider this the following March.

1040 See the chapter on *People’s Experiences*.

1041 See detailed discussion below on the Wessex lookback.

1042 AIDS - Chief Medical Officer’s Statement 20 December 1984 p2 BART0000814

1043 *The Guardian* reported that her baby had also been infected. *The Guardian Blood donor passes Aids virus to baby/Brighton* 20 December 1984 NHBT0000024\_005

1044 AIDS - Chief Medical Officer’s Statement 20 December 1984 p2 BART0000814

1045 Dr Hewitt was a consultant haematologist at the North London Blood Transfusion Centre and managed their HIV lookback programme; she was later national clinical lead for Transfusion Microbiology. Written Statement of Dr Patricia Hewitt para 171 WITN3101006 (emphasis in original).

1046 The terms of reference for this group were: “*To consider the implications for the National Blood Transfusion Service of testing blood donations for antibody to HTLV III and to report.*” List of members of Advisory Committee on the NBTS regarding the Working Group on AIDS November 1984 p1 CBLA0001934\_002



were being considered by the IMCD division of the DHSS.<sup>1047</sup> 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”*.<sup>1048</sup> The reference to *“counselling”* concerns the question of how to communicate to recipients of a transfusion that they had received infected blood and/or were HIV positive as a result. This was not akin to the modern use of the word referring to psychological support: rather it involved telling the patient of their HIV infection, giving basic advice, and referring the individual on to specialist services. Dr Vanessa Martlew described it as a process to *“gently inform, advise and refer”*.<sup>1049</sup>

On 30 November 1984 Dr Craske wrote to haemophilia centre directors setting out future plans for investigating the cause of AIDS for people with haemophilia. The process was to be changed because the retrospective studies undertaken into patients who had received batches of Factor 8 linked to AIDS cases in 1983 at Bristol Haemophilia Centre had shown that it was *“impossible to identify implicated batches of factor VIII with certainty by retrospective serological testing for seroconversion to anti-HTLV-3 positive.”* This was said to be because the prevalence of the HTLV-3 antibody in people with haemophilia treated with commercial factor products was between 50% and 80%, the number of infected batches they were treated with might be quite high, and the limited sera available made it difficult to identify the date of seroconversion within a limit of 6-12 months. Facilities for testing HIV were *“in short supply”*, so it was decided that further investigations should focus on those with clinical features suggestive of AIDS and on prospective studies involving batches of Factor 8 *“possibly contaminated”* with HIV.<sup>1050</sup>

On 14 December 1984 the United Kingdom Haemophilia Directors’ Organisation (“UKHCDO”) produced an AIDS Advisory Document which summarised recommendations made at a recent meeting of haemophilia reference centre directors.<sup>1051</sup> In the main this dealt with recommendations for treatment and arrangements for testing. However, in relation to lookback it was noted that *“recipients”* of at least one BPL and one Scottish batch of Factor 8 *“are being followed up.”*<sup>1052</sup>

At the first meeting of the Expert Advisory Group on AIDS (“EAGA”) on 29 January 1985, the need for AIDS counselling was acknowledged. St Mary’s Hospital in Paddington, London, was noted to have done *“Much excellent work in this field”* and was a *“possible choice”* for a national centre for training health professionals in AIDS counselling. It was agreed that counselling *“must be available at the point when an individual is first told that he has AIDS and/or a positive test for HTLV III antibody, and should preferably be provided by the person*

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1047 The DHSS Communicable Diseases Division.

1048 Memo from Dr Abrams to Dr Harris 27 November 1984 DHSC0002251\_011

1049 Dr Martlew was the Liverpool regional transfusion director. Written Statement of Dr Vanessa Martlew para 559 WITN4034001

1050 Letter from Dr Craske to Haemophilia Centre Directors 30 November 1984 HCDO0000392\_107

1051 AIDS Advisory Document 14 December 1984 HCDO0000270\_007. The meeting involved Drs Lane, Cash, Gunson, Mortimer, Tedder, and Craske amongst others.

1052 AIDS Advisory Document 14 December 1984 p2 HCDO0000270\_007

*who imparts this information.*” A small working group was established to provide advice on AIDS counselling.<sup>1053</sup>

On 28 March 1985 EAGA’s Screening Test Sub-Group met. The meeting focused on issues of testing and consent. It was noted that all individuals with positive results “*must be told because of the dangers to their health and that of others*”.<sup>1054</sup>

When EAGA met on 29 May 1985, they discussed a paper from the Sub-Group on AIDS Counselling which indicated that those who received counselling “*modified their sexual behaviour and that counselling also alleviated distress and confusion.*” It was recommended that two types of counselling training should take place. The first, which was a priority, was a “*brief course*” lasting two days that was aimed at providing “*basic counselling skills*”. The second was a more detailed course “*lasting for a month for those intending to run their own AIDS counselling courses and those responsible for a large number of patients with AIDS related problems.*”<sup>1055</sup>

On 10 June 1985 the EAGA Screening Test Sub-Group met again. The bulk of the meeting focused on the arrangements for testing. However, there was discussion about the “*follow up of earlier positive donations*”<sup>1056</sup> noting that where “*long-standing donors were found to be antibody positive, it was agreed that only physicians should be informed (via the haematologist). It would be for the physician to decide further action. This line would be presented to the EAGA.*”<sup>1057</sup>

Dr Hewitt describes this discussion as marking “*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.*”<sup>1058</sup> It is not known why an emphasis was put on long-standing donors, rather than those who had only recently started giving blood or donors giving blood for the first time. It is also unclear which donors were defined as “*long-standing*”.

With evaluation of HIV screening tests about to start, the regional transfusion directors met on 10 July 1985 and agreed that where an HTLV-3 positive donation was found, the initial approach to the donor would be from NBTS and afterwards counselling would be “*essential*” with GPs involved with the donor’s consent.<sup>1059</sup> EAGA was to be the source of specific guidelines, to inform which a working party would “*draft a flow diagram for AIDS testing and*

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1053 Minutes of EAGA meeting 29 January 1985 pp3-4 PRSE0002734

1054 Emphasis added. Note of EAGA meeting 28 March 1985 p1 DHSC0001571

1055 Minutes of EAGA meeting 29 May 1985 p3 PRSE0002837

1056 The time period of what “*earlier*” positive donations means is not specified.

1057 Note of EAGA meeting 10 June 1985 p4 DHSC0000551

1058 Written Statement of Dr Patricia Hewitt para 178 WITN3101006

1059 It should be noted that whereas Dr Gunson had been told a year earlier that a recipient’s GP should be told of their at risk status “in confidence” (ie without telling the patient) the principle now being adopted was almost diametrically opposed: the patient was to be told without also telling the GP (unless the patient wanted that). Instead of the GP being in control of the information, the patient was to be.

*following up of donations.*” It was agreed that the follow up of previous donations of plasma should be for a period of three to five years. Dr Richard Tedder had requested that reporting of post-transfusion illnesses that were probably infective should be made to him.<sup>1060</sup>

The following day the working party produced a report on the Screening of Blood Donations for anti-HTLV-3 in RTCs. Procedures for testing donations were set out in full as well as the follow-up for HTLV-3 positive donations.<sup>1061</sup> This appears to be the “*first fully articulated policy*” for lookback after the introduction of testing.<sup>1062</sup> The procedure for following up recipients of previous donations given by an infected donor was:

*“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 seropositivity of the donation given to the Consultant in charge of the patient.*

*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.”*<sup>1063</sup>

By the time EAGA met on 30 July 1985, Dr Gunson and his colleagues were advising that screening could start in October 1985.<sup>1064</sup> Dr Gunson said that if a blood donor tested positive a letter would be sent by the RTC and an appointment arranged for the donor to be interviewed “*by a doctor trained in counselling.*”<sup>1065</sup> The DHSS briefed that funding was being provided to expand the AIDS counselling course at St Mary’s. A clinical psychologist and a health adviser were being recruited and preferential spaces on the course were being given to “*personnel from the BTS and STD clinics on a regional basis initially.*” 160 people were to be trained prior to the introduction of HIV screening. It was hoped that there would be “*several individuals in each region who had attended a counselling course by the time the test came into use.*” EAGA agreed that “*an evaluation*” of the course was an “*important part of this service*” and a revised proposal was awaited from St Mary’s.<sup>1066</sup>

With regard to lookback, EAGA agreed that “*the haematologist in charge of the hospital blood bank should be informed if it was believed that an earlier donation could have transmitted HTLVIII infection. The haematologist would be asked to identify the recipient of the suspect donation and to inform the clinician in charge of the case when the blood*

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1060 Minutes of Regional Transfusion Directors meeting 10 July 1985 pp3-4 CBLA0002212

1061 Screening of Blood Donations for Anti-HTLV III in Regional Blood Transfusion Centres 11 July 1985 pp1-4 DHSC0000406

1062 Written Statement of Dr Patricia Hewitt para 183 WITN3101006

1063 Screening of Blood Donations for Anti-HTLV III in Regional Blood Transfusion Centres 11 July 1985 p4 DHSC0000406

1064 Minutes of EAGA meeting 30 July 1985 p4 PRSE0002628, Screening of blood donations for anti-HTLV III in Regional Blood Transfusion Centres – Correction DHSC6887757\_124

1065 Minutes of EAGA meeting 30 July 1985 p4 PRSE0002628

1066 Minutes of EAGA meeting 30 July 1985 p7 PRSE0002628

*had been transfused.*<sup>1067</sup> EAGA considered that it would be for the clinician in charge of the patient to decide on any investigations and that follow up for donations “*should go back a minimum of five years from the date of the donation*” even though this might mean there were “*practical difficulties.*”<sup>1068</sup> It was noted that the “*BTS was aware of the importance of good record keeping to enable the follow up of donations.*”<sup>1069</sup>

EAGA met again on 1 October 1985. Dr Acheson noted that the second edition “*in the Blue Book series*” had been distributed to all doctors in England with a parallel exercise taking place in Scotland, Wales and Northern Ireland. This booklet included “*simplistic advice on the counselling of a positive patient.*” Dr Acheson was noted to be “*sceptical*” about the number of doctors who would read the booklet as he was “*aware of a recent survey of London general practitioners which showed a considerable degree of ignorance about HTLV III infection and AIDS. This indicated they had not read the first Blue Book.*” There was a broader discussion about counselling positive patients. It was said by Professor Alistair Geddes that the “*complexities of counselling were being over-estimated*” and that any GP or consultant was capable of counselling patients. He described that the counselling he gave consisted of an explanation of the significance of a positive test to a patient’s health and the risk to other people.<sup>1070</sup> It was noted that many patients asked if they could return with their families for further counselling. Discussion followed about the aim to create a pool of AIDS counsellors throughout the UK with a special one-day course for GPs. The need for counselling courses outside of London was raised and Dr Cash noted that the St Mary’s counselling team were “*prepared to organise courses at other centres.*”<sup>1071</sup>

As part of the AOB section of the meeting, and thus an apparent afterthought, an important topic was raised. Dr Marcela 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’s view was that “*the scheme should be extended to cover all HTLV III positive patients.*”<sup>1072</sup>

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1067 This suggests that the clinician should be told, and says nothing about whether the patient should be. It is contrary to the principle which had been agreed earlier that same month by the regional transfusion directors (see above). It appears to put the clinician in the case in charge of disclosure of the information, rather than the patient to whom it related.

1068 Minutes of EAGA meeting 30 July 1985 p5 PRSE0002628. Again, this appears to agree that the clinician was to make the decision. The approach of the Medical Ethics Expert Group to the Inquiry is that the patient’s autonomy should be respected: it is for the patient, albeit with the advice of a treating professional, to make the decisions which may affect their future. Expert Report to the Infected Blood Inquiry: Medical Ethics April 2020 p68 INQY0000241. So far as public health considerations are concerned (preventing an infected person passing on the disease to others) there is no statement here that the clinician should take any particular steps.

1069 Minutes of EAGA meeting 30 July 1985 p5 PRSE0002628. The paper for this part of the discussion was produced by the EAGA Screening Sub-Committee: Follow Up of Blood Donations Previously Given by Donors who are Identified as Positive for HTLV III Antibody DHSC0002273\_064

1070 Minutes of EAGA meeting 1 October 1985 p5 MRCO0000001\_068. As described earlier, this was a health practitioner passing on information to a patient about AIDS rather than addressing any psychological consequences of patients being told that they were likely to die within a short period of time from a (then) untreatable condition.

1071 Minutes of EAGA meeting 1 October 1985 p8 MRCO0000001\_068

1072 Minutes of EAGA meeting 1 October 1985 p10 MRCO0000001\_068

## Lookback processes from October 1985 (after universal screening)

On 14 October 1985 HIV screening was introduced throughout the UK.<sup>1073</sup> EAGA met on 26 November 1985 and was updated on the screening of donations. Discussions were ongoing about increasing the number of training courses for counselling, as well as collaborating with the British Association of Counselling.<sup>1074</sup>

At the close of the meeting, again almost as a postscript, Dr Tedder asked, on behalf of Dr Contreras, if clinical members would consider asking seropositive patients as a matter of routine if they had donated blood since 1978. In cases where blood had been donated, members were asked to refer their patients to the RTC so that the recipients of such blood donations could be followed up. Dr Michael Abrams, now chairing, noted *“that this needed to be considered by the full Group at its next meeting.”*<sup>1075</sup>

At the next meeting, held on 15 January 1986, no progress had been made in relation to proposals to extend the counselling provided by St Mary’s to other parts of the country.<sup>1076</sup>

For the third time, Dr Contreras requested that clinicians should *“as a matter of routine ask patients with HTLV III antibodies or AIDS if they had donated blood and where”* and report those who had to the relevant regional transfusion director. Dr Gunson thought this could be difficult for sexual health clinics, given the confidentiality of the information: *“in his view it would be better if the patients were asked to report to the Director.”*<sup>1077</sup> The chairman said that this would be included in the next CMO letter.

A “Dear Doctor” letter was sent from the CMO to all doctors in England in April 1986. At the end of the short letter, the CMO asked clinicians to enquire whether any HTLV-3 patients had previously been blood donors. The CMO stated that *“it would be helpful to discuss this in an appropriate confidential manner with your Regional Transfusion Director.”*<sup>1078</sup> This came some six months after screening had been introduced in the UK, rather than having been anticipated in advance of the introduction of universal screening as an important aspect of public health protection.

At a meeting of the haemophilia centre directors AIDS Group on 2 July 1986 it was noted that there had been *“frequent complaints via the Haemophilia Society about apparently*

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1073 DHSS Press Release: All Blood Donations now being Screened for Antibodies to the AIDS Virus 14 October 1985 NHBT0004299. See the chapter on *HIV Screening*.

1074 Minutes of EAGA meeting 26 November 1985 p2 DHSC0002287\_060

1075 Minutes of EAGA meeting 26 November 1985 p12 DHSC0002287\_060

1076 Minutes of EAGA meeting 15 January 1986 p4 DHSC0000833. The March meeting of EAGA was briefed that funding proposals had been submitted for an extra 1,500 places on counselling courses at St Mary’s, Birmingham and Manchester in the next financial year. Some of the courses would be open to wider groups of health professionals and local authority staff working with people with AIDS. Minutes of EAGA meeting 11 March 1986 p12 DHSC0001499

1077 Minutes of EAGA meeting 15 January 1986 p11 DHSC0000833

1078 Letter from Dr Acheson to all doctors in England 23 April 1986 p3 BART0000737



*appalling low standards of counselling at some Centres.*<sup>1079</sup> There were different views of the usefulness of the St Mary's course.<sup>1080</sup> A counselling day for haemophilia staff was therefore arranged.<sup>1081</sup> In October 1986, it was noted that money for AIDS counselling had been provided to *"each of the Reference Centres in England but not to the Reference Centres in Scotland and Wales. Belfast was still endeavouring to get funds for this purpose."*<sup>1082</sup>

Curiously, on 8 October 1986 at a meeting of regional transfusion directors, in the context of a discussion about participation in an epidemiological study of patients who had received infected blood, proposed by Dr Tim Wallington of Bristol, the issue of *"what action should be taken about informing recipients of HIV infected blood"* arose again. It appears that this was being discussed as a general issue, beyond the specific concerns arising from the study. It was agreed that the first step was that the clinician in charge of the recipient's case should be approached. Opinion was *"divided"* about the correct approach if a clinician was unwilling to act. In particular, concern was expressed about a clinician being unwilling to act in cases involving younger patients.<sup>1083</sup> During this meeting it was also noted that when tracing the recipients of donations from a HIV-positive donor, finding that a recipient had died was *"not necessarily the end of the story"* as the recipient's organs may have been used for transplantation.<sup>1084</sup>

Dr Hewitt emphasised in her evidence to the Inquiry, that it is not clear why as late as October 1986 a discussion about informing recipients of HIV-infected blood was still ongoing, when this issue had been addressed as part of the introduction of screening of blood in the UK in 1985.<sup>1085</sup>

## Reports, evaluations and the Eileen Trust

Dr Craske shared interim results from a retrospective study of HIV infections associated with NHS Factor 8 and 9 at a UKHCDO meeting on 9 October 1986.<sup>1086</sup> He stated that he thought there was *"under-reporting from the Directors and about 30% under-reporting of AIDS/ARC cases nationally generally to CDSC."*<sup>1087</sup> He supplied a specific confidential form for clinicians to send to Oxford for the follow up of batches of NHS Factor 8. The

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1079 Minutes of Haemophilia Centre Directors AIDS Group meeting 2 July 1986 p2 HCDO0000271\_066

1080 The AIDS counselling experts at St Mary's were described as having a *"lack of understanding ... of the special problems of haemophiliacs"*, though Dr Irvine Delamore had found his course there very useful. Professor Bloom had raised concerns about the St Mary's courses at EAGA on 15 January 1986. Minutes of Haemophilia Centre Directors AIDS Group meeting 2 July 1986 p2 HCDO0000271\_066, Minutes of EAGA meeting 15 January 1986 p3 DHSC0000833

1081 Minutes of Haemophilia Centre Directors AIDS Group meeting 2 July 1986 p2 HCDO0000271\_066

1082 Minutes of UK Haemophilia Centre Directors meeting 9 October 1986 p3 PRSE0004317

1083 Minutes of Regional Transfusion Directors meeting 8 October 1986 pp1-2 CBLA0002345

1084 Minutes of Regional Transfusion Directors meeting 8 October 1986 p2 CBLA0002345. The Inquiry has received evidence of this. Written Statement of ANON WITN2781001 and the section on the North West RTC below.

1085 Written Statement of Dr Patricia Hewitt para 192 WITN3101006

1086 Retrospective Study of HIV Infection Associated with Unheated NHS Factor VIII and IX 10 September 1986 DHSC0001039

1087 Minutes of UK Haemophilia Centre Directors meeting 9 October 1986 p4 PRSE0004317

form included a list of clinical features and the date that such symptoms first appeared.<sup>1088</sup> Dr Craske said that the “*only real way to judge the safety of materials was to do a careful study like the one the Directors were doing*” ie following up on batch numbers.<sup>1089</sup>

In December 1987 Dr Craske produced a paper making recommendations for the future monitoring of infections transmitted by Factor 8 and 9 concentrates. This was based on information collected over a period of 10 years by the UKHCDO’s Hepatitis Working Party as well as its AIDS Group. As part of a wider systematic review of the implications of blood products, he proposed that in cases of suspected HIV a “*careful history to establish the probable batch involved*” should be undertaken along with “*the clinical and serological surveillance of others who have received material from the suspect batch.*” He recommended the establishment of a Blood Product Surveillance Working Party with representation of haemophilia centre directors, BPL, DHSS and PHLS with the monitoring organised from Oxford Haemophilia Centre. Features of it were that “*The system would be voluntary; physicians would be encouraged to co-operate actively in the investigation of every incident.*” The “*follow-up of patients would be instituted where appropriate in collaboration with a patient’s physician.*”<sup>1090</sup>

On 19 February 1990 Dr Gunson produced a report addressing the testing of blood for HIV in the UK from 1985 to 1989. He stated that since screening had been introduced 150 confirmed seropositive cases had been found, an incidence of 1 in 75,000 donations.<sup>1091</sup> Of 24 male donors who were found seropositive in 1989, 14 were “*established donors*”.<sup>1092</sup> Of five now seropositive female donors, three previous donations had been seronegative. He stated that “*attempts are made to recall all confirmed anti-HIV positive donors to the RTC for interview and counselling as appropriate.*” It was noted that there had been “*in general*” no investigations into cases where individuals had received blood from seronegative donations from a donor who “*subsequently became seropositive*”, but where there had been investigations, the patient was found either to have died from the primary condition from which they were suffering when transfused, or were seronegative for HIV. He noted as an exception the seroconversion of two patients in Glasgow “*following the transfusion of products from a donor who was anti-HIV negative in July 1986 and positive in October 1986*”, which was identified as the “*first formally documented*” example of a window period transmission.<sup>1093</sup> Dr Hewitt explained in her evidence to the Inquiry a practical limitation to

1088 Retrospective Study of HIV Infection Associated with Unheated NHS Factor VIII and IX 10 September 1986 p5 DHSC0001039

1089 Minutes of UK Haemophilia Centre Directors meeting 9 October 1986 p5 PRSE0004317

1090 Recommendations for the Future Surveillance of Infection Transmitted by Factor VIII and IX Concentrates 15 December 1987 pp1-2 HCDO0000427

1091 The risk factor for one (possibly two) donors was thought to be a blood transfusion. Anti-HIV 1 Testing of Blood Donations in the UK 1985-1989 19 February 1990 p8 NHBT0015578\_001

1092 Anti-HIV 1 Testing of Blood Donations in the UK 1985-1989 19 February 1990 p2 NHBT0015578\_001. These figures demonstrate the importance of avoiding a regular repeat donor putting more people at risk. It helps to underline the case for lookback to trace recipients who had been put at risk through earlier transfusions.

1093 Anti-HIV 1 Testing of Blood Donations in the UK 1985-1989 19 February 1990 p3 NHBT0015578\_001, Written Statement of Dr Patricia Hewitt para 206 WITN3101006

the HIV lookback in this period: *“At that time, the only means of communicating with donors was by letter to the last recorded address held on the blood centre records. There was no facility to trace individuals by other means, such as through NHS records, a facility which became available at a much later date and made a huge difference to the ability to trace individuals who had moved house and changed address.”*<sup>1094</sup>

On 11 September 1990 a report was produced by Dr Janet Mortimer of PHLS examining the NBTS lookbacks from October 1985 to December 1989. The coverage of the report was incomplete<sup>1095</sup> but it found that, between October 1985 and December 1989, 67 repeat donors were found to be anti-HIV positive. Information was available in relation to the follow-up of previous donations for 64 of them. They had given at least 419 donations in total. A quarter of these donors had given six or more donations previously. Most donations were given before routine anti-HIV testing began. However, 39 donations had been given since the introduction of screening: *“all but one was negative”*. No seroconversions had been found in the recipients of this blood but it was noted that follow up had not been completed in all cases because of *“patient deaths from underlying causes, difficulties in identifying recipients and reluctance to alarm patients”*. HIV transmission could therefore not be ruled out.<sup>1096</sup>

Dr Mortimer’s report found *“differences in follow-up capacity and practice between centres; the lack of computerised records can be a limitation, and while some centres have pursued every identifiable donation, others have curtailed look-back when they have identified a negative recipient or have evidence that the donation predates infection. There are also gaps when donors have moved between regions.”*<sup>1097</sup>

Dr Mortimer concluded that *“greater uniformity of practice seems desirable”*. She made the following suggestions:

- “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, or 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 donating screening.*

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1094 Written Statement of Dr Patricia Hewitt para 17 WITN3101019

1095 The report did not cover Scotland nor did it cover all recorded transfusion-associated HIV infections from RTCs in England, Wales and Northern Ireland because cases of positive recipients found through reverse lookbacks were not included.

1096 NBTS Look-Back October 1985 - December 1989 11 September 1990 p1 NHBT0015574\_002

1097 NBTS Look-Back October 1985 - December 1989 11 September 1990 p1 NHBT0015574\_002

4) *That the results of the look-back be recorded on a form such as ... Appendix 2 and collected and collated centrally on an annual basis.*<sup>1098</sup>

These suggestions were considered by EAGA on 2 October 1990. The group supported the continuation of the lookback study, and agreed to Dr Mortimer's recommendations, but considered that previous investigations should be pursued until two anti-HIV negative recipients had been identified rather than just one as proposed by Dr Mortimer.<sup>1099</sup>

Although screening for HIV had begun in October 1985 and lookback had been recognised as an important part of the UK's response to HIV from the outset,<sup>1100</sup> this appears to be the first formal report analysing the HIV lookback. It was published almost five years after the date when HIV screening was first introduced in the UK. Dr Hewitt describes Dr Mortimer's report as "*one of the more complete records of some of the work that the blood services did on lookback*" and that it "*happened without a unified structure for the English blood service, and relied to a large extent on consensus for compliance by all RTDs.*"<sup>1101</sup>

On 8 May 1991 Dr Mortimer wrote to regional transfusion directors asking for the latest information they could give on recipients of blood from a donor subsequently found to be positive and "*those for whom transfusion has been ruled out as the likely source of infection and those whose position is unresolved.*" To facilitate follow-up she offered to check the databases at CDSC, "*in confidence, to see if any donors you have not been able to contact may have been reported as HIV positive or as an AIDS case.*"<sup>1102</sup>

By February 1992 it was noted at a meeting of DHSS officials, CDSC and Dr Gunson that about 90% of all HIV positive donors who could be traced had been informed of their HIV status and told not to donate again. "*NBTS would be in a position to find the donation number from the hospital and trace back to the donor. Where a donor moves from one RTC to another a transfer note should be held to enable the donor to be traced.*"<sup>1103</sup> *Difficulties could arise where perhaps as many as 30 units used in one transfusion would need to be traced.*"<sup>1104</sup>

This meeting occurred at a time when the government had announced that individuals infected with HIV by way of blood or tissue transfer would be included within a payment

1098 NBTS Look-Back October 1985 - December 1989 11 September 1990 p2 NHBT0015574\_002

1099 Minutes of EAGA meeting 2 October 1990 p3 NHBT0008213\_002

1100 See for example, 4 April 1984 meeting between Dr Galbraith and Dr Gunson described above. Note of meeting about surveillance of AIDS in relation to Blood Transfusion 4 April 1984 CBLA0001833

1101 Written Statement of Dr Patricia Hewitt paras 215-217 WITN3101006

1102 If the clinician wanted this done, they were asked to supply the "Soundex" code and date of birth. That data would then be kept "*on file for checking against new reports at quarterly intervals thereafter.*" Letter from Dr Mortimer to Regional Transfusion Directors 8 May 1991 p2 NHBT0004801. Further details were set out in the letter about creating a Soundex code: see Letter from Dr Mortimer to Regional Transfusion Directors 8 May 1991 pp4-5 NHBT0004801. This was a confidential code to prevent individuals' real names being used.

1103 Dr Hewitt's evidence is that a note would only be held where "*the donor had notified us.*" Written Statement of Dr Patricia Hewitt para 226 WITN3101006

1104 Minutes of DHSS/CDSC/NBTS meeting 21 February 1992 p2 DHSC0002941\_006

scheme.<sup>1105</sup> This created a renewed focus on the issue of HIV lookback. It was plainly helpful to be able to identify both those patients who were thought to be infected as the result of a transfusion or transplant, and (to help to verify any claims already made and lead to the identification of further such claims) to identify from whom infected donations might have come.

The recently appointed CMO, Dr Kenneth Calman, wrote to a wide range of clinicians and public health professionals about recipients of infected donations. He asked for help in identifying patients who might be entitled to payment under the recently introduced payment scheme. Regional transfusion directors were asked to “*check their records and remind consultants of any donations from donors subsequently found to be HIV positive.*” All consultants and GPs were also asked to consider their patient lists. Dr Calman stated that the CDSC would write “*on a confidential basis*” to consultants who had already reported cases to them.<sup>1106</sup>

Dr Gunson also wrote to all regional transfusion directors in respect of those who might have donated infected donations. He asked that any blood donations “*which may be implicated in transmitting HIV to patients as a result of blood transfusion*” be identified. The names of blood donors found to be HIV positive since testing started were sought, along with a list of donation numbers, the dates of delivery, the consultant haematologist involved and the hospital concerned. Dr Gunson noted that “*some of you may already have this information available from ‘look-back’ programmes.*”<sup>1107</sup>

This highlights the absence of a centralised, nationwide and comprehensive database of people infected with HIV which could have enabled a more extensive lookback exercise to be undertaken.<sup>1108</sup> The involvement of the CMO at this point is also notable in that, other than the “Dear Doctor” letter, a CMO had not pressed for a comprehensive lookback until this time despite this intervention carrying “*considerably more weight than Dr Gunson trying to convince clinical colleagues by persuasion.*”<sup>1109</sup>

## Variations in practice between and within the four nations

Lookback in respect of HIV was a UK-wide policy. It was introduced in the four nations at the same time, when screening began in October 1985. However, HIV lookbacks in Northern Ireland and Wales were rare. There was some variation in practice across and

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1105 See the chapter on the *Eileen Trust*.

1106 Letter from Dr Calman to all Hospital Consultants and General Practitioners in England 30 April 1992 30 April 1992 p1 OXUH0001251\_004

1107 Letter from Dr Gunson to all Regional Transfusion Directors 11 May 1992 NHBT0015108

1108 Attention is drawn above to the poor record keeping. It was, in general terms, the responsibility of the DHSS and Scottish Home and Health Department (“SHHD”) to have ensured better (though the input into records would in the first place necessarily be that of individual clinicians and their hospitals, or GPs and their practices, as well as the blood services and BPL/Plasma Fractionation Laboratory/ Protein Fractionation Centre). The absence of a database as identified in the text is a fact: it is regrettable that it was the case that there was none, but this is best seen not as a separate criticism but as a specific aspect of the failure to keep good records.

1109 Written Statement of Dr Patricia Hewitt para 232 WITN3101006



within the four nations. This was largely dependent on the number of lookback exercises, and therefore the experience that staff had in undertaking them. The depth of lookback was very staff dependent. This was not least because of the significant time commitment involved given the difficulties in obtaining medical records. Practice also appears to have changed over time.

## Scotland

In Scotland there was no formal lookback policy issued governing the lookback but Scottish regional transfusion directors agreed to adopt the 11 July 1985 working party recommendation endorsed by EAGA.<sup>1110</sup> On 4 October 1985 at a meeting for medical staff held at Scottish National Blood Transfusion Service (“SNBTS”) headquarters it was agreed that individual doctors would be required to undergo training at St Mary’s Hospital, Paddington.<sup>1111</sup>

Dr Jack Gillon was a member of the Working Party on Transfusion Practice and HIV in Scotland from 1987 to 1989 and was in charge of the HIV lookback for Edinburgh and South East Scotland Blood Transfusion Service. When a donor tested positive, he was responsible for obtaining the donation records. He next sought to obtain the hospital notes, where available. He wrote to the patient’s consultant to inform them that his or her patient had received blood that was possibly infected with HIV, and to offer to inform the patient informally. It was “*almost invariably*” the case that Dr Gillon would be asked by the patient’s clinician to meet with the patient to “*break the news*”. He would therefore write to the patient and arrange an appointment. He would “*then follow the counselling and testing protocol, see the patient again if necessary, and inform the consultant and the patient’s GP if the patient consented, then make appropriate follow up arrangements.*” Dr Gillon created a specific case record, which was kept in a locked filing cabinet in his office.<sup>1112</sup>

The need for lookbacks was uneven. For example, at the Aberdeen and North East Blood Transfusion Service, for the first four years after testing started, “*we did not have anything to look back on*” because no HIV positive donors were identified.<sup>1113</sup>

For the Penrose Inquiry the SNBTS produced a paper entitled *Procedures to identify, trace and offer counselling and testing to patients who received blood components from donors subsequently found to be positive in tests for HIV and HCV*. The outcome of this paper was that “*from a starting point*” of 39 anti-HIV positive donors with previous donations, a targeted lookback undertaken by the SNBTS resulted in nine anti-HIV positive patients being identified. The number of patients confirmed or accepted as probable cases of transfusion-

1110 Written Statement of Dr Jack Gillon to the Penrose Inquiry pp1-2 PRSE0000623, Screening of Blood Donations for Anti-HTLV III in Regional Blood Transfusion Centres 11 July 1985 p4 DHSC0000406

1111 Written Statement of Dr Jack Gillon to the Penrose Inquiry p3 PRSE0000623

1112 Written Statement of Dr Jack Gillon paras 247-248 WITN6987001

1113 Written Statement of Professor Stanislaw Urbaniak para 228 WITN6960001. Professor Urbaniak was the regional director designate and consultant in transfusion medicine at Aberdeen and North East Scotland Blood Transfusion Service from 1982 and became the regional director in March 1983.

transmitted HIV was eight. (One further case of transfusion transmitted HIV was found when investigations were undertaken for the purposes of Penrose.)<sup>1114</sup>

## Northern Ireland

Dr Morris McClelland, director of the Northern Ireland Blood Transfusion Service (“NIBTS”), was involved in the establishment of a lookback process for HIV in Northern Ireland. He states that when a confirmed positive blood donor was found a lookback process was followed “*from the outset*”. However, such occurrences were rare and so the procedure followed was “*a relatively informal and ad-hoc process*”. The haematologist in charge of the hospital blood bank would be informed of the donation numbers and advised on the importance of trying to identify recipients, in conjunction with the clinician involved.<sup>1115</sup> No extra funding was sought or obtained for it.<sup>1116</sup> Dr McClelland personally managed the donor counselling and lookback process in relation to the first positive HIV donor after attending a training course in London.<sup>1117</sup> Dr Chitra Bharucha, consultant clinical haematologist and deputy director of NIBTS from 1981 to 2000, recalls “*only vaguely*” that a lookback programme was implemented.<sup>1118</sup> To the best of her recollection, there were two confirmed HIV positive donors in Northern Ireland. Both of them were female and neither of them had donated blood “*for many years, if at all.*” In order to “*maintain confidentiality in a small community*”, with the patients’ consent, she telephoned their GPs herself.<sup>1119</sup>

## Wales

A search of the blood transfusion archives in Wales has failed to identify specific documents relating to an HIV lookback.<sup>1120</sup> Documents considered by the Penrose Inquiry suggest that a lookback exercise was undertaken in Wales upon the introduction of screening for HIV.<sup>1121</sup>

Dr Tony Napier, medical director of the Welsh Regional Blood Transfusion Service from 1977-1990, recalls that HIV positive donations were “*exceptionally rare*” with about one per annum in Wales.<sup>1122</sup>

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1114 Lookback: Procedures to identify, trace and offer counselling and testing to patients who received blood components from donors subsequently found to be positive in tests for HIV and HCV pp9-10 PRSE0004042

1115 Written Statement of Dr Morris McClelland p88 WITN0892001

1116 Written Statement of Dr Morris McClelland p112 WITN0892001

1117 Written Statement of Dr Morris McClelland pp112-113 WITN0892001. Subsequent cases were managed by Dr Chitra Bharucha.

1118 Written Statement of Dr Chitra Bharucha para 104 WITN6967001

1119 Written Statement of Dr Chitra Bharucha paras 67, 105 WITN6967001

1120 Written Statement of Catherine O’Brien paras 416, 428 WITN6876001. A diagram was produced in 2018 apparently setting out the “*WBS pre testing HIV Donor Seroconversion look backs*” WITN6876050. However, the source of the data in this diagram is not known and it has not been possible to check the accuracy of this data. Written Statement of Catherine O’Brien para 417 WITN6876001

1121 Written Statement of Catherine O’Brien para 416 WITN6876001

1122 Written Statement of Dr John Napier para 246 WITN6915001

## England

The rigour with which various regions approached lookback varied from one to another.

### Wessex

Particular difficulties appear to have arisen with early lookback exercises. In late September/early October 1984 a blood donor was admitted to Bournemouth Hospital with a “*skin rash consistent with Kaposi’s sarcoma, leukopenia and anaemia.*” He had given a donation of plasma in Wessex on 27 March 1984 which had been dispatched to BPL on 6 April 1984. It was used in the production of a batch of Factor 8, number HL3186, at BPL which was distributed to Wessex RTC on 10 August 1984 and to Cardiff RTC on 15 August 1984.<sup>1123</sup>

Dr Smith of the Wessex RTC was notified by telephone that HL3186 might be infective, and was asked to recall all vials of the batch of Factor 8 including those provided for home therapy. He was also asked to report any plasma from the donor dispatched to BPL or the Plasma Fractionation Laboratory within the last five years and to determine whether the donor had a “*history of attendance at local special clinics for venereal disease.*” Similarly, the Cardiff RTC was informed by telephone on 3 October 1984 and asked to recall vials of HL3186. Dr Craske of PHLS was consulted and asked for a list of haemophilia centres that were supplied with HL3186 so a follow-up could be initiated.<sup>1124</sup>

The donor had given a total of four blood donations which were identified. Three were in Bournemouth, in September 1983, March 1984 and September 1984. They were all of whole blood. The first and second of these were sent to a Portsmouth hospital, the first as whole blood and the second as red cells. The plasma recovered from this second Wessex donation was sent to BPL and it was this which infected the relevant batch. The third donation, which had been given only a week before he was admitted to hospital with Kaposi’s sarcoma and other signs of AIDS, was intercepted at the RTC.<sup>1125</sup>

However, he had also given blood on 21 November 1982 at Leeds, and time expired plasma from this donation had been sent to BPL on 11 January 1983.<sup>1126</sup>

The way this was handled gives rise to a number of issues.

First, on 4 October 1984 a notification letter was sent by Dr Michael Barnes, deputy medical director of the Wessex RTC, to the haemophilia centre directors in the Wessex region to recall unused Factor 8 from batch HL3186. The letter explained that a donor who contributed to it was “*now thought to be suffering from AIDS*” though a diagnosis would take a week or

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1123 Plasma Incident Report No 115 2 October 1984 p1 CBLA0000010\_183. 485 vials went to Wessex; 400 to Cardiff, and from there was distributed in smaller quantities to Heath Park, Morriston, and Carmarthen hospitals as well as being used in Cardiff.

1124 Plasma Incident Report No 115 2 October 1984 CBLA0000010\_183

1125 He gave blood despite having engaged in high-risk homosexual activity – and despite his condition a week later his donation was accepted. It fortunately was subsequently discarded. Letter from Dr Michael Barnes to Dr Terence Snape 4 October 1984 p1 CBLA0000010\_209

1126 Plasma Incident Report No 115 2 October 1984 p2 CBLA0000010\_183. Batch number C3162.

two but *“In order to prevent undue worry to your patients”*, he asked them *“for the time being at least, to keep this new[s] to yourself.”*<sup>1127</sup> He did not however alert either of the clinicians involved in the use of the donations sent to Portsmouth: *“We are not getting in touch with the clinicians involved until the diagnosis is confirmed.”* He did not provide any justification for this approach of waiting for a confirmed diagnosis notwithstanding his understanding of the donor’s clinical presentation (*“almost certainly, AIDS”*).<sup>1128</sup>

Recall arrangements were instituted in Cardiff.<sup>1129</sup> However, Dr Barnes re-emphasised his request for information to be kept quiet: *“I have been asked to suggest that a policy of discrete surveillance be pursued.”*<sup>1130</sup> The previous explanation given for this *“discretion”* was the lack of a diagnosis.<sup>1131</sup> This rationale patently no longer applied.

Funding had been allocated to the PHLS to follow up recipients on the Wessex batch, as well as batches of US-derived Factor 8 known to be associated with donors with AIDS.<sup>1132</sup>

Dr Terence Snape produced a report into this matter, dated 23 October 1984. His observations were: *“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.”*<sup>1133</sup> Just under four years later Dr Craske expressed frustration at the quality of the follow-up: *“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.”*<sup>1134</sup> He expressed concern that he did not know the outcome of patients who had received that and other batches which might have contained HIV.<sup>1135</sup>

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1127 Letter from Dr Barnes to Haemophilia Centre Consultant Haematologists 4 October 1984 DHSC0002247\_090

1128 Letter from Dr Barnes to Dr Snape 4 October 1984 p1 CBLA0000010\_209

1129 Letter from Dr Napier to Dr Snape 8 October 1984 CBLA0000010\_212

1130 Letter from Dr Barnes to All Directors of Haemophilia Centres in Wessex 16 October 1984 DHSC0002247\_093

1131 Letter from Dr Barnes to Haemophilia Centre Consultant Haematologists 4 October 1984 DHSC0002247\_090

1132 Memo from Dr Smithies to Dr Alderslade 19 October 1984 p2 DHSC0002323\_009

1133 Summary report on the recall of Factor VIII batch HL3186 occasioned by probable diagnosis of AIDS in a contributing donor 23 October 1984 p5 DHSC0001111

1134 Letter from Dr Craske to Dr Lane 23 September 1988 CBLA0000010\_202. Whereas there was plainly a lack of rigour in relation to the incident at Bournemouth, after the first person with haemophilia in the UK died from AIDS in August 1983, having been a patient at Bristol and treated with commercial factor concentrate in December 1981, Dr Craske and others on the UK Working Party on Transfusion-Associated Hepatitis resolved that *“All batches of NHS and commercial concentrate and cryo since 1st Jan 1980 will be followed up and other recipients checked.”* Minutes of UK Working Party on Transfusion Associated Hepatitis meeting 27 September 1983 p2 PRSE0001299

1135 Letter from Dr Craske to Dr Lane 23 September 1988 CBLA0000010\_202

### *Oxford Blood Transfusion Centre*

Donations were tested at Oxford from 7 October 1985 with a temporal scope of six (rather than the national standard of five) years.<sup>1136</sup> Dr Colin Entwistle, director of the Oxford Blood Transfusion Centre from May 1980 to September 1995, described an “*ad hoc system*” in place for carrying out investigations into HIV as this was “*not a regular routine activity. On the other hand, obviously, when a positive case turned up, it would be necessary to go back and see what we can find by way of further information about the same donor.*”<sup>1137</sup> The only such case he personally experienced was in around 1985 or 1986 when a young woman came to the Oxford Regional Transfusion Centre who he is “*almost certain*” was a new donor. She attended a session and tested positive for HIV. After discussion with her, he referred her to the GP and to a local haematologist. In this case there was no lookback undertaken because “*her case was very clear cut in identifying the time of infection.*”<sup>1138</sup>

### *North London Blood Transfusion Centre*

The North London Blood Transfusion Centre (“NLBTC”) was at the forefront of the HIV lookback in England: Professor Contreras, deputy director and consultant in blood transfusion, described NLBTC as “*the first centre to introduce a HIV look-back programme, based in our region.*”<sup>1139</sup> The processes they followed were particularly detailed and thorough. Dr Patricia Hewitt, consultant haematologist of the NLBTC from 1984, managed the HIV lookback programme.<sup>1140</sup> It started in 1985 and covered central and northwest London, Bedfordshire, Hertfordshire and parts of Berkshire.<sup>1141</sup> In her oral evidence to the Inquiry on the lookback steps undertaken by the NLBTC she stated that the Centre “*would pursue it until we had an outcome*”.<sup>1142</sup> Professor Contreras outlined the following steps taken at NLBTC for the HIV lookback:

*“We followed up, in detail, all reports from hospitals of possible transfusion transmitted infections by testing the patients’ blood samples and, if confirmed, by investigating the archive samples of the donations involved and, when appropriate, by contacting the relevant donors. If specific donors were found to transmit infections, then we counselled them and removed them from the donor panel; we studied the risk factors for their carrier status. If new risk factors were found, we modified our donor selection criteria accordingly.”*<sup>1143</sup>

The lookback process was subsequently refined further: “*HIV was not common in 1980 and 1981, going back five years all at once was pursuing some donations which may not have*

1136 Letter from Dr Colin Entwistle to Dr Snape 13 January 1986 BPLL0010773

1137 Dr Colin Entwistle Transcript 6 December 2021 p108 INQY1000167

1138 Written Statement of Dr Colin Entwistle paras 86, 151 WITN6917001

1139 Written Statement of Professor Dame Marcela Contreras para 347 WITN5711001

1140 Written Statement of Dr Patricia Hewitt paras 4-5 WITN3101006

1141 Written Statement of Dr Patricia Hewitt para 5 WITN3101006

1142 Dr Patricia Hewitt Transcript 9 December 2021 p175 INQY1000170

1143 Written Statement of Professor Dame Marcela Contreras para 355 WITN5711001



*been a risk, and so we refined it by going back sequentially. So we would do the most recent donation first and if we got a positive outcome from that, that there was an infected recipient we would then go back to the next previous one, and so on.*"<sup>1144</sup> They would investigate until there were two consecutive negatives rather than going back the full 5 years. There was no direct contact with the recipient initially, though they later took on that role if asked, and the Centre was reliant on the information provided by the hospital.<sup>1145</sup>

A valuable review of the lookback scheme at NLBTC was undertaken by Dr Hewitt in 1993. It looked both at tracing recipients from infected donors and donors from infected recipients. 22 recipients of transfusions were thought to have been infected as a result of transfusions; 25 donors were identified as HIV positive. As a result of the study, 5 transfusion recipients who had not previously been known to be HIV positive were identified; and 2 people previously known to be HIV positive were shown probably to have been infected as a result of a transfusion (which had not previously been realised). In her conclusions Dr Hewitt noted that no cases of transmission by transfusion had arisen in the Centre since screening began in 1985. While laboratory record keeping had improved, accurate recording of transfusion details in patient medical records remained a conspicuous problem up to the date of the report.<sup>1146</sup>

#### *North West RTC*

Similarly detailed processes appear to have been followed at the North West RTC. Dr Martlew conducted HIV lookback exercises in Manchester following the introduction of routine donor screening.<sup>1147</sup> This included a particularly poignant case. A patient suffered a serious accident. He died. Before he died, he received a unit of blood during attempted resuscitation that was subsequently shown to come from an HIV positive donor. The patient was an organ donor. As a result of the transfusion, his kidney was infected. It was transplanted to a renal patient, who became infected in turn.<sup>1148</sup> The recipients of the donor's other kidney, liver and heart were also traced and identified to be HIV positive.<sup>1149</sup>

When she was working in Liverpool, Dr Martlew recalls that when undertaking HIV lookbacks the DHSS "*insisted*" that the prescribing clinician or GP should approach the patient before a clinician at the regional blood centre, but "*Usually both treating hospital clinicians and GPs declined and the Transfusion Centre Consultants would see the recipients, arrange testing and onward referral. This meant that in practice the correspondence with those clinicians*

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1144 Dr Patricia Hewitt Transcript 9 December 2021 pp175-176 INQY1000170

1145 Dr Patricia Hewitt Transcript 9 December 2021 pp175-177 INQY1000170

1146 Investigation of Possible Transmission of HIV by Blood Transfusion 13 May 1993 p2, pp11-13 DHSC0006351\_032

1147 Consultant haematologist North West Regional Transfusion Service 1984-1988. Written Statement of Dr Vanessa Martlew para 371 WITN4034001

1148 Written Statement of ANON WITN2781001

1149 Letter from Consultant Surgeon to Mr Morton 28 September 1992 pp2-3 WITN2781002. One organ donor's infection had caused HIV infections in four people who received transplants.

who had been directly involved with patients to assist in the process, usually merely delayed the process.”<sup>1150</sup> She is critical of this approach:

*“it often fell to blood service consultants to provide this service to transfusion recipients on the basis that treating clinicians and GPs more often than not declined. These were obviously people (unlike doctors) with whom we had no prior direct therapeutic or other clinical relationship which meant that they were hearing this news from strangers rather than from clinicians they might have known for a long time, felt comfortable with and trusted.”*<sup>1151</sup>

### Yorkshire RTC

In Yorkshire, Dr Angela Robinson recalled that at the Yorkshire Regional Blood Transfusion Centre they did not have many donors who tested positive.<sup>1152</sup> When a donor tested positive a lookback was performed on prior donations: *“We would have to go through the hospital blood bank to find out whether the donation had been transfused and if so to whom. Once we had passed the information on to the blood bank it was the blood bank’s responsibility to trace where the donation had gone.”*<sup>1153</sup> In the context of lookback, in contrast to a blood donor testing positive, the Centre *“did not really have direct contact with the recipient.”*<sup>1154</sup> That was left to clinicians. She, too, stated that hospital records were the *“main insufficiency when it came to locating recipients of blood and blood products.”*<sup>1155</sup>

## Epidemiological study

Dr Wallington attempted to gather epidemiological data from HIV lookbacks but this was abandoned in the early 1990s.<sup>1156</sup>

The draft documents accompanying a proposed epidemiological study in May 1986 emphasised that some people infected with HIV via transfusions *“have not been identified.”* Many were individuals likely to fall outside high risk groups. Therefore it could *“be argued these people and their close contacts should be identified and counselled for their own sakes.”* It had *“been agreed that an attempt be made to identify and study these patients and their household contacts.”* The suggested starting point was donors identified by screening since 14 October 1985. It was further noted that there were *“instances in which patients infected by blood transfusion have brought the problem to light and a donor can be found by*

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1150 Written Statement of Dr Vanessa Martlew paras 374-375 WITN4034001

1151 Written Statement of Dr Vanessa Martlew para 564 WITN4034001

1152 Consultant in clinical haematology and blood transfusion to the YRTC 1976 to 1988 and chief executive to the YRTC from 1988 to 1994, as well as medical director of the National Blood Authority from 1994 to 2005 and medical director of NHS Blood and Transplant from 2005-2007. Written Statement of Dr Angela Robinson para 141 WITN6926001

1153 Written Statement of Dr Angela Robinson para 214 WITN6926001

1154 Written Statement of Dr Angela Robinson para 323 WITN6926001

1155 Written Statement of Dr Angela Robinson para 326 WITN6926001

1156 Letter from Dr Wallington to Dr Cash 30 May 1986 SBTS0000033\_066, Letter from Dr Contreras to Dr Gunson 2 January 1991 NHBT0000052\_033, Letter from Dr Wallington to Dr Gunson 20 February 1991 NHBT0004810

*back tracing.*<sup>1157</sup> The study would involve tracing recipients of infected donors and donors of infected recipients and also household contacts and seeking consent for their data to be included in the epidemiological study.<sup>1158</sup>

Dr Wallington sent the proposal to the chairman of the British Medical Association’s ethics committee who advised that it be sent to seven ethics committees selected randomly in England and Wales. The first was the ethics committee at Southmead Hospital which rejected it, with two physicians on the panel arguing that *“in no circumstances would their patients be approached to take part in such a study.”*<sup>1159</sup> It appears that the study had not yet got off the ground by November 1986: Dr Gunson wrote then to Dr Wallington referring to the *“enormity of the task”*.<sup>1160</sup>

In May 1987 Dr Wallington sent the study documents to RTCs and asked that they inform haematologists and sexual health specialists in their region, saying that *“Epidemiologically important information which is not being collected at present is likely to accrue from analysis of the answers.”* While 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.”*<sup>1161</sup>

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 [sic] about investigation of household contacts. Opinion has been changing rapidly and most people now believe that infected persons should be identified whenever 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.”*<sup>1162</sup>

Not only ethics, but also funding raised its head. Dr Martlew, though broadly supportive of Dr Wallington’s study, foresaw *“difficulties in obtaining co-operation of consultant colleagues, particularly in G.U.M [genitourinary medicine]”* unless there was funding for completing the forms. She also thought that *“detailed interrogation of recipients, and especially their families, may be resisted locally on the grounds of generating panic in the community.”* She

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1157 Covering Letter to Epidemiological Study pp1-2 DHSC0002480\_047, Letter from Dr Wallington to Dr Cash 30 May 1986 SBTS0000033\_066

1158 Anti-HTLV III Tests on coded samples from PHLS p1 NHBT0004204, Covering Letter to Epidemiological Study p3 DHSC0002480\_047

1159 Minutes of Regional Transfusion Directors meeting 8 October 1986 p1 CBLA0002345

1160 Letter from Dr Gunson to Dr Wallington 4 November 1986 NHBT0017052

1161 Letter from Dr Wallington to Dr Gunson 6 May 1987 pp1-2 NHBT0004202

1162 Letter from Dr Wallington to Dr Gunson 6 May 1987 p2 NHBT0004202

considered that the “*special attention paid to HIV positive subjects will be difficult to conceal, confidence not withstanding. This might well have unpleasant social consequences.*”<sup>1163</sup>

Finally, a lack of enthusiasm hampered efforts. By July 1987 Dr Wallington was writing to Dr Gunson stating that he had received “*very little comment or information*” since he distributed the material in May.<sup>1164</sup>

It appears the study was abandoned in the early 1990s despite some RTCs sending data to Dr Wallington.<sup>1165</sup> In her evidence to the Inquiry Dr Hewitt stated that there were resource difficulties and a “*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.*”<sup>1166</sup>

## Was the UK’s HIV lookback effective?

The UK’s HIV lookback had the potential to be broadly effective, largely because it was commenced at the same time as screening and fairly close in time to when likely infections took place. The 1990 reports both of Dr Gunson in February, and of Dr Mortimer in September, show that the lookback had identified a number of potential infections, and enabled the damage they could cause to be contained. The experience of Dr Hewitt showed how, if driven forward, the lookback was of real value to individuals in identifying or helping to avoid infections.

The value of HIV lookback was not merely about preventing future infections but also enabled family members to understand what had happened to their loved ones. For example a widow describes that being told about her husband’s HIV infection by way of lookback exercise some nine years after his death provided comfort as it “*was nice to finally know [his death] was out of my husband’s control and that it was someone else’s fault.*”<sup>1167</sup>

However, there were a number of limitations to the UK’s HIV lookback. These are addressed below.

### Deficiencies in record keeping

The most significant limitation of the HIV lookback was the failure to have a complete set of medical records and blood bank records when tracing suspect batches or donations.

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1163 Memo from Dr Martlew to Dr Gunson 26 May 1987 NHBT0004200

1164 Letter from Dr Wallington to Dr Gunson 22 July 1987 p1 NHBT0004199

1165 Letter from Dr Contreras to Dr Gunson 2 January 1991 NHBT0000052\_033, Letter from Dr Wallington to Dr Gunson 20 February 1991 NHBT0004810

1166 Written Statement of Dr Patricia Hewitt para 200 WITN3101006

1167 Written Statement of ANON paras 22, 30 WITN0407001

Guidance at the time emphasised the importance of record keeping for patients receiving blood.<sup>1168</sup> It had done so for years. It was recognised by the World Health Organization Expert Committee on Hepatitis in 1952.<sup>1169</sup> The guidance *Notes on Transfusion* set out the need to have a record of every transfusion in a patient’s case notes and that it was “*not always appreciated that the main reason for accurate recording is the protection of the patient.*”<sup>1170</sup> However, this did not occur in practice. Frequently there was no written evidence in the medical records that a patient had had a transfusion, and similarly batch numbers for blood products were often missing from medical records.<sup>1171</sup> In these instances it was therefore impossible to trace a suspect batch or donation.

In Scotland, Dr Gillon described that “*the biggest problem by far*” was missing hospital records or the failure to have a record of where the blood component went: “*it made it impossible to trace quite a substantial percentage of the components.*”<sup>1172</sup> SNBTS reported to the Penrose Inquiry that “*blood bank and hospital records are seldom available from the pre-computer era, so that it is virtually impossible to trace the fate of donations from the early 1980s and before. Even in the mid-to late 1980s, many blood banks relied on paper systems which were difficult to search systematically. It is therefore frequently impossible to establish whether, and to whom, a blood component was transfused.*”<sup>1173</sup>

Similar issues were present in England. Dr Hewitt writing in 1993 stated that when undertaking HIV lookbacks it was “*not uncommon to find that a hospital laboratory has records of issuing a donation for a particular recipient, but the medical notes contain no information about the donations transfused. Such an omission obviously leaves room for doubt when investigating possible cases of transfusion transmitted infection.*”<sup>1174</sup>

Dr Robinson told the Inquiry that “*The ease of implementing the lookback depended on the state of the paper records held by the centre and the degree of computerisation and the response of hospital blood banks.*”<sup>1175</sup> Although computerisation was introduced in some regions, different RTCs introduced different systems.<sup>1176</sup> In Yorkshire, when the transfer from paper to computer records took place, those donors who had not donated for “*say, five years plus*” were not transferred onto the computer system.<sup>1177</sup> Dr Robinson’s understanding was

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1168 See the chapter on *Blood Transfusion: Clinical Practice*.

1169 World Health Organization Expert Committee on Hepatitis March 1952 p20 RLIT0000215

1170 Emphasis in the original (1963). The Ministry of Health in association with the Scottish Home and Health Department *Notes on Transfusion* 1963 p17 JPAC0000162\_021

1171 See the chapter on *People’s Experiences*.

1172 Dr Jack Gillon Transcript 19 January 2022 p73 INQY1000173

1173 Lookback: Procedures to identify, trace and offer counselling and testing to patients who received blood components from donors subsequently found to be positive in tests for HIV and HCV p11 PRSE0004042

1174 Paper titled Investigation of Possible Transmission of HIV by Blood Transfusion by Dr Hewitt 13 May 1993 p11 DHSC0006351\_032

1175 Written Statement of Dr Angela Robinson para 592 WITN6926001

1176 Written Statement of Dr Angela Robinson paras 328-329 WITN6926001

1177 Written Statement of Dr Angela Robinson para 333 WITN6926001



that the paper records were archived, rather than destroyed. In Northern Ireland, however, six files addressing lookback from 2000 to 2006 have been lost.<sup>1178</sup>

In addition to difficulties with hospital records and blood bank records, a further problem arose with the absence of contact details for recipients. For example, where individuals moved house and were no longer registered with the same GP who was caring for them at the time of transfusion, tracing recipients was challenging.<sup>1179</sup> One example is that in March 1993 the South Thames Blood Transfusion Service carried out a lookback in which out of 23 implicated donors, 11 were “lost to follow-up.”<sup>1180</sup> It was noted that “a significant number were from a local college and had moved on.”<sup>1181</sup>

### **No centralised database of HIV positive donors and patients**

The absence of a complete, centralised database listing all HIV infected donors and patients meant that there was duplication in lookback exercises and there was no clear pathway to identify if a donor had also donated in another region, wherever it was in the UK.

There was a database of infected donors kept at the CDSC but it appears to have been limited. In 1993 Dr Hewitt noted that it was of “*continuing concern to the BTS that there is no mechanism for checking whether a lapsed donor has subsequently been reported as HIV positive through the confidential reporting system operated by the Communicable Disease Surveillance Centre.*”<sup>1182</sup>

Some individual RTCs kept their own databases of HIV positive donors. For example, Professor Contreras states that the NLBTC kept its own list of HIV positive donors and “*communicated with the CDSC to add information to the database that they kept.*”<sup>1183</sup>

A database was produced in Scotland:

*“In the early years following the introduction of HIV antibody testing a system for centralised collation of data from all 5 Scottish Regional Transfusion Centres was established at the national microbiology reference laboratory (MRU), based in Ruchill Hospital in Glasgow, where confirmatory testing for all regional laboratories was carried out. At the same time (1985) Health Protection Scotland (HPS, then known as SCIEH) developed a database to gather data from request forms for HIV testing from all laboratories in NHS Scotland. SNBTS readily agreed to participate in this, while still maintaining and managing SNBTS data.”*<sup>1184</sup>

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1178 See Written Statement of Karin Jackson para 31 WITN2681034; see also Written Statement of Dr Kieran Morris para 25 WITN3922001

1179 Paper titled Investigation of Possible Transmission of HIV by Blood Transfusion by Dr Hewitt 13 May 1993 p11 DHSC0006351\_032

1180 Letter from Sue Knowles to Dr Andrzej Rejman 16 March 1993 DHSC0014978\_092

1181 Letter from Sue Knowles to Dr Andrzej Rejman 16 March 1993 DHSC0014978\_092

1182 Paper titled Investigation of Possible Transmission of HIV by Blood Transfusion by Dr Hewitt 13 May 1993 p12 DHSC0006351\_032

1183 Written Statement of Professor Dame Marcela Contreras para 277 WITN5711001

1184 Written Statement of Dr Jack Gillon para 98 WITN6987001

However, prior to the establishment of the national computer system in Scotland in the mid to late 1990s, there was no way to check if a donor had donated in another region if the donor did not volunteer that information,<sup>1185</sup> let alone in England, Wales or Northern Ireland.

The lack of a centralised database meant that some individuals, who were infected with HIV after receiving blood and/or blood products, were missed by the national lookback. For example, one individual received blood transfusions as a young child for acute lymphoblastic leukaemia from June 1982 to 1984. They only received an HIV diagnosis in 1994 when they were 15 years old.<sup>1186</sup> The diagnosis occurred because of their deteriorating health, rather than being identified by an HIV lookback exercise.

### **The effectiveness of exclusionary measures**

The ability of the blood services to determine whether a donor had HIV depended on the donor returning to give blood. It was only then that her or his blood would be screened as a matter of course.<sup>1187</sup> If the donor was shown to have HIV, then it would be realised they might well have been infected at the time of their earlier donations. Efforts could then be made to trace recipients of those donations. However, if a donor did not return to give blood later – perhaps because, now knowing they were considered to belong to an “at risk” group of people, they chose to self-exclude – there would be no way of knowing if the donation (or donations) they had given previously might have been infected. The number of people identified by a targeted, “going to whom?” lookback was thus always going to be limited.

Measures taken by the regional transfusion directors to encourage at risk donors to self-exclude from donating blood meant that fewer donors were re-tested. Dr Hewitt’s evidence is that:

*“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.”<sup>1188</sup>*

Dr Jean Harrison’s evidence to the Inquiry is that *“donor self-exclusion had been very efficient so very few donors were actually found to be positive. I do think that, in general,*

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1185 Dr Jack Gillon Transcript 19 January 2022 pp73-74 INQY1000173

1186 Written Statement of ANON paras 13-14 WITN0267001

1187 Written Statement of Dr Patricia Hewitt para 187 WITN3101006

1188 Written Statement of Dr Patricia Hewitt para 187 WITN3101006

*donors were responsible and did not wish to harm others by donating their blood if they thought they were at risk.*<sup>1189</sup>

### The lack of government guidance

No formal lookback scheme or policy was published, though an approach was agreed by EAGA. However no guidance was produced to encourage clinicians to ask patients whether they had donated blood beyond brief inclusion in a CMO's "Dear Doctor" letter.<sup>1190</sup> This was a potentially important omission because the success of individual HIV lookbacks throughout the country depended on clinicians actively asking HIV positive patients about their donor status. This issue was raised three times by Dr Contreras and Dr Tedder at EAGA meetings.<sup>1191</sup> Writing in 1993 Dr Hewitt highlighted the "*failure of professionals to ask*" infected individuals about prior blood donations and then to notify the RTC, and noted that this led to "*missed opportunities to identify all recipients infected with HIV by transfusion.*"<sup>1192</sup> She told the Inquiry that it was only "*Infrequently*" that a person who was HIV positive was asked whether they had been a blood donor and the relevant RTC informed; she considered that formal guidance on this topic "*might have been something which would have been taken on board.*"<sup>1193</sup>

Top-down guidance or advice could have played a particularly significant role in light of the decentralised nature of blood services in the UK during the 1980s. Dr Gunson had no executive authority to impose a single standardised approach to RTCs in relation to lookback.<sup>1194</sup> He could not require any approach, let alone standardise one, as between different regions. Dr Mortimer in her September 1990 report noted that there were disparities in the approaches that different RTCs took in relation to HIV lookbacks.<sup>1195</sup>

Dr Hewitt has highlighted that "*the main thrust*" of HIV lookback in England in the 1980s took place within a context where there was "*no national organisation of the English blood service.*" She notes that "*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.*"<sup>1196</sup> Consequently, best practice in terms of consistently asking an HIV positive patient about whether they had previously donated blood and in the thoroughness of tracing could not be ensured across the UK.

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1189 Dr Harrison was director at the North East Thames RTC. Written Statement of Dr Jean Harrison para 471 WITN7046001. It was also reported as a problem in the US. See Busch *Let's look at human immunodeficiency virus look-back before leaping into hepatitis C virus look-back* Health Policy 1991 pp3-4 PRSE0004329

1190 Dr Patricia Hewitt Transcript 9 December 2021 p177 INQY1000170, Letter from Dr Acheson to all doctors in England 23 April 1986 BART0000737

1191 See above.

1192 Paper titled Investigation of Possible Transmission of HIV by Blood Transfusion by Dr Hewitt 13 May 1993 p12 DHSC0006351\_032

1193 Dr Patricia Hewitt Transcript 9 December 2021 pp174, 178 INQY1000170

1194 Written Statement of Dr Harold Gunson in *A v National Blood Authority* Judgment March 2000 pp5-6 NHBT0000026\_009

1195 NBTS Look-Back October 1985 – December 1989 11 September 1990 pp1-2 NHBT0015574\_002

1196 Written Statement of Dr Patricia Hewitt para 299 WITN3101006

## Clinician enthusiasm

The Inquiry has received evidence which demonstrates that some clinicians were less than enthusiastic about undertaking lookback due to the intensive nature of a lookback exercise.

Dr Hewitt explained that *“Sometimes the RTC has written to five or six doctors in an individual case (haematologist, surgeon, physician, referring physician, GP) without any of them wishing to take responsibility for notifying the recipient.”* This created not only an increased workload but also a delay in reaching the patient.<sup>1197</sup>

One example of lack of enthusiasm for a lookback is found when BPL requested a lookback in relation to some batches of Factor 8. In response, in a letter dated 3 October 1985 a consultant haematologist at Wessex RTC, stated: *“Logistically it is going to be impossible for us to scrutinize 1500 donors from so long ago, and both Dr. Smith and I agreed that we would ensure any of our HTLVIII a/b positives do not include the donors mentioned by checking prospectively.”*<sup>1198</sup> Dr Lane of the BPL chased this lookback and highlighted that the Factor 8 batches related to a potential HIV seroconversion in a young person with haemophilia.<sup>1199</sup> Dr Smith from the Wessex RTC then agreed to check the Centre’s records.<sup>1200</sup>

## Counselling

As noted above, “counselling” was used to refer to informing patients that they had received infected blood, rather than providing psychological support to patients. Many clinicians attended AIDS counselling training at St Mary’s. Dr Martlew’s evidence was that she

*“went on the first ever course on counselling for patients with HIV at St Mary’s Paddington, which addressed how to break such terrible news. At the time my understanding of ‘counselling’ in this context referred to the approach to providing information for and advice to donors who had the results of a positive screening test confirmed and prior to referral on to the appropriate specialist for further investigation and any appropriate treatment.”*<sup>1201</sup>

Dr Harrison describes that when a donation was found to be infected with HIV, the donor was *“initially counselled by an NBTS consultant and a trained counsellor from their local hospital. NBTS consultants were trained in HIV counselling by a team from St Mary’s Hospital, Paddington.”* She states that *“it was not long”* until there were specialist HIV counsellors available in hospitals.<sup>1202</sup>

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1197 Paper titled Investigation of Possible Transmission of HIV by Blood Transfusion by Dr Hewitt 13 May 1993 pp11-12 DHSC0006351\_032

1198 Letter from Dr Jayaswal to Dr Snape 3 October 1985 CBLA0000010\_227

1199 Letter from Dr Lane to Dr Smith 20 October 1988 CBLA0000010\_229

1200 Letter from Dr Smith to Dr Lane 26 October 1988 CBLA0000010\_230

1201 Written Statement of Dr Vanessa Martlew para 561 WITN4034001

1202 Dr Harrison was also Consultant Haematologist of NHS Blood and Transplant from 1995 to 2011. Written Statement of Dr Jean Harrison paras 462-463 WITN7046001

For the experiences of individuals of the counselling available upon HIV diagnosis, see the chapter on *People's Experiences*.

## Commentary

The picture in relation to HIV lookback is mixed.

Much good was achieved by it, and it ought to be recognised that much hard work was given by a number of clinicians in achieving this against the considerable pressures of work, time and finance. Those who helped make it, overall, reasonably effective deserve credit for doing so. Further infections were prevented and individuals were enabled to plan their futures knowing of their infection. The risks that individuals might, for a while, not realise that they were infected and during that period might transmit HIV to others were reduced.

There were some delays that should not have occurred.

If a person was infected they may in the past have given a donation of infected blood. In that way, they have passed on the infection, unknowingly, to someone else. A chain of transmission could be set up from one person to another. Public safety, as well as proper treatment of the recipients of any infected donation they may have given, demanded proper efforts to identify whether a person now known to be suffering from HIV infection had been a donor in the past, and if so when. It was easy to do: by making it routine for doctors to ask anyone presenting to them with HIV if they had ever given blood. Only Dr Contreras and Dr Tedder seem to have spotted this, and for them to have to raise it three times at EAGA between October 1985 and January 1986 meant that six months were lost before the CMO letter in April 1986 rather than it being part of the national approach to one route of transmission.

Two further failures of much longer duration contributed to difficulties in lookback. The first of those was a failure to keep proper records. The poor quality of the keeping of medical records has been a constant theme throughout almost all aspects the Inquiry is tasked to consider. It ought never to have been that way. The need for accurate and full records of transfusions, from donor to recipient, had been known for over 30 years before HIV lookback began. A failure of care, or casual indolence or the lack of an understanding of the importance of records could and should have been addressed long before the events which gave rise to this Inquiry. It still needs to be emphasised today. This was not a failure attributable to any specific minister, civil servant, NHS body, clinician or other institution: rather, the responsibility was a general one, shared by all those involved in the health service over decades, to ensure that there was a proper system for record keeping and that the system was working as well as it could, to recognise when proper recording was not happening, and to encourage those who should put entries into records to regard that as an important part of their duties.

The second is a delay in relation to England and Wales: the fractured nature of the Blood Transfusion Service meant that studies could not be done and that information received in



one region was not easily shared with another. This is something which had been identified for some years before the twin crises of HIV and non-A non-B Hepatitis infections.<sup>1203</sup>

Those both affected the quality and effectiveness of the lookback when it occurred.

As to the lookbacks themselves, it took too long to resolve ethical concerns. The approach taken initially to telling patients information about their own health betrays an uncomfortable, and wrong, paternalism. There was too much concern about causing “alarm” or “panic” which should have little place in a mature pluralistic democracy, where citizens are properly to be regarded as capable of knowing what is awkward and unpleasant as well as that which is welcome and pleasant. Where information concerns them personally, held by someone who owes them professional responsibility, they should be told.

There was no sufficient mechanism in England for checking to see whether a lapsed donor had subsequently been reported as HIV positive through the confidential system operated by the CDSC. Scotland was better served, though there was no check on whether a donor had donated in another region.

Nonetheless, these deficiencies, and the other shortcomings identified in the body of the narrative, should not detract from the point made at the start of this commentary, that – in general, and despite them – the lookback operated effectively to prevent a number of infections and what would at the time have often been their fatal consequences.

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1203 See the chapters on the *Blood Services and Addressing Risk*.

## 5.7 Hepatitis C Lookback

This chapter focuses on the implications of a four and a half year gap between the introduction of an effective screening test for Hepatitis C and a UK-wide lookback. It examines why there was a delay, the impact of such a delay, and problems in the implementation of the lookback scheme that was conducted.

### Key dates

**May 1989** test for Hepatitis C becomes available.

**27 June 1990** NBTS and SNBTS liaison committee agrees that it would not be appropriate to establish a lookback policy, though France has one.

**2 July 1990** ACVSB postpones decision on Hepatitis C lookback.

**21 November 1990** ACVSB is told ACTTD will consider, and takes no decision.

**22 November 1990** Professor Cash asks that ACVSB consider lookback.

**8 January 1991** ACTTD recognises there is ethical obligation to tell recipients.

**25 February 1991** ACVSB recommends that a lookback should not be undertaken.

**13 August 1991** ACTTD decides a Hepatitis C lookback should be considered.

**1 September 1991** UK introduces screening of blood donations for Hepatitis C

**September 1991** Dr Gillon begins a look-back in Edinburgh and SE Scotland, in the guise of a “pilot” scheme.

**18 May 1994** SNBTS proposes to start lookback on 1 June.

**5 August 1994** SACTTI concludes there is a moral obligation to tell recipients.

**December 1994** Dr Gillon’s study on lookback published.

**15 December 1994** MSBT recommends lookback programme.

**16 December 1994** ministerial submission advises lookback.

**22 December 1994** Scottish minister writes to the Department of Health that lookback is a matter of legal liability and must take place as soon as possible in Scotland.

**4 January 1995** ministerial agreement to lookback.

**11 January 1995** UK-wide Hepatitis C lookback programme announced

**April 1995** UK-wide Hepatitis C lookback begins.

### People

**Professor John Cash** national medical director, SNBTS

**Dr Jack Gillon** consultant, South East Scotland BTS

**Dr Harold Gunson** medical director, National Blood Authority (1993 - 1994)

**Dr Jeremy Metters** deputy chief medical officer, MSBT chair, ACVSB chair

**Dr Angela Robinson** medical director, National Blood Authority (1994 - 2005)

### Abbreviations

**ACTTD** Advisory Committee on Transfusion Transmitted Diseases

**ACVSB** Advisory Committee on the Virological Safety of Blood

**MSBT** Advisory Committee on the Microbiological Safety of Blood and Tissue for Transplantation

**SACTTI** Standing Advisory Committee on Transfusion Transmitted Infections

Although an effective screening test for Hepatitis C was introduced in September 1991, it was another four and a half years before a UK-wide Hepatitis C lookback was undertaken. This chapter examines why there was a delay in undertaking a national Hepatitis C lookback and the impact of such a delay, as well as problems in the implementation of the lookback that was conducted.<sup>1204</sup>

Prior to the establishment of a national Hepatitis C lookback in April 1995, some regional transfusion centres (“RTCs”) throughout the UK undertook ad hoc Hepatitis C lookbacks.

In 1989, the need for a national Hepatitis C lookback began to be discussed. Many individuals working within the blood transfusion services, in government and in the Civil Service had experience of the earlier UK-wide HIV lookback.<sup>1205</sup> However, there was little appetite for a national Hepatitis C lookback because of the apparent difficulty of the task and the cost and resource implications.<sup>1206</sup> In these discussions little, if any, consideration was given to the interests of those who had unknowingly received blood or blood products infected with Hepatitis C.

During the first years of the 1990s, a further reason given for not conducting a lookback was that there was no effective treatment for Hepatitis C. The argument was that individuals who were unknowingly infected with Hepatitis C should not be told of their infection because it would distress them to know about it, and that there was no effective treatment to give them. This was especially so, it was said, because the condition might be asymptomatic and might not develop into a symptomatic illness for many years.<sup>1207</sup>

This medical paternalism did not give adequate consideration to the rights of individuals to know their own health status. Its impact on some individuals and their families was severe. Individuals unaware of their infections suffered from a constellation of symptoms but never knew their cause. They did not know when, or if, they should seek medical attention. They were in no position to take decisions that might improve their health, such as limiting alcohol intake. Although sexual and secondary transmission are rare,<sup>1208</sup> individuals who were unknowingly infected were unable to take any precautions they may have wished to take: and since such transmission did occur, both risked the health of their partners and families and (later) were exposed to the horror of knowing that they could have done. Those who were diagnosed as carrying the virus were often advised not to share toothbrushes or combs, and to take care to avoid inadvertent transmission in the home: that advice implied that there were steps which both could and should have been taken by individuals to avoid infecting those nearest to them. Not to tell them that they posed such a risk to others, small though it may have been on an individual level, failed those members of the public who were

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1204 This chapter concerns the lookback relating to recipients of transfusions and people who received blood products who were not under the care of a haemophilia centre. Testing for Hepatitis C for people with bleeding disorders is addressed in the chapters on *Haemophilia Centres: Policies and Practice* and *People’s Experiences*.

1205 See the chapter on *HIV Lookback*.

1206 As discussed below.

1207 Written Statement of Dr Angela Robinson para 418 WITN6926003

1208 Expert Report to the Infected Blood Inquiry: Hepatitis January 2020 pp11-12 EXPG0000001

being unwittingly put at risk. It represented a failure to protect public health. Yet it appears that such factors were not considered by the Department of Health at the time of deciding whether to carry out a Hepatitis C lookback.<sup>1209</sup>

Gradually, and due to the persistence of a handful of individuals working in the blood transfusion services as well as the actions of campaigners and journalists, momentum for a Hepatitis C lookback began to gather pace. In Scotland in particular, there was a drive to establish a lookback in mid 1994. Some Hepatitis C lookbacks were undertaken before the national lookback was announced in April 1995. Such lookbacks were done on a pilot and research basis. However, there was then further delay due to the view that it was more important to co-ordinate a single UK-wide policy than proceed to lookbacks in particular areas where these could be performed earlier.<sup>1210</sup>

The evidence demonstrates that across the UK a lookback could and should have been established at or immediately after the time that testing was introduced. This Report has also found that testing itself should have been introduced by March 1990. Had that been done, it would follow that a lookback could and should have been initiated at that stage.

Analysis of internal UK government material reveals that the Government's decision to introduce the Hepatitis C lookback in April 1995 was a reactive one, based on pressure arising from articles in the media, the instigation of legal claims and concerns about the need for a formal lookback from individuals working in blood services.<sup>1211</sup> Westminster's position was also adopted in Wales and Northern Ireland. From late 1994 onwards the discussion about whether to have a national Hepatitis C lookback began to be framed in terms of an existence of a duty of care towards donors and recipients.<sup>1212</sup> It is unclear why such a duty of care could be framed and articulated in late 1994 but not any earlier.

As a result of the delay in introducing the Hepatitis C lookback, its effectiveness was hampered. In contrast to the position with HIV, by the time the Hepatitis C lookback was undertaken the infective agent of Hepatitis C had been present for a long time in the UK blood supply. There were significant difficulties tracing donors and patients due to a lack of complete transfusion and hospital records. Due to the delay, many donors and recipients had died, moved house or changed names through marriage, and were no longer contactable.

This chapter first considers the early hepatitis lookbacks, then considers the steps taken before and after the introduction of Hepatitis C screening and addresses the effectiveness of the national Hepatitis C lookback.

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1209 Dr Andrzej Rejman Transcript 11 May 2022 pp158-160 INQY1000204

1210 There are echoes here of the way in which Hepatitis C screening was itself delayed in many parts of the country because of the desire to have a single UK-wide position all would adopt at the same time.

1211 See for example Submission from Roger Scofield to the Parliamentary Under-Secretary of State for Health 22 December 1994 pp1-2 DHSC0032208\_149

1212 See for example Draft Report from the Advisory Committee on the Microbiological Safety of Blood and Tissue ("MSBT") Subcommittee 15 December 1994 NHB T0005791

## Early jaundice lookbacks

From the 1940s onwards, lookback investigations were undertaken in relation to jaundice. Medical officers of the Ministry of Health published a memorandum in *The Lancet* in January 1943 about incidences of jaundice. The need for accurate records was highlighted as well as the need for “*the speedy notification by practitioners to transfusion officers of cases of jaundice following, after a long interval, the injection of blood products.*”<sup>1213</sup>

Cases of jaundice following blood transfusion were investigated. As early as 14 January 1948 Dr William d’A Maycock emphasised the need to establish a reporting system for cases of haematogenous<sup>1214</sup> hepatitis. Donors were removed from the donor pool when homologous serum jaundice was suspected and specific pro forma records were to be filled out.<sup>1215</sup> However, the available documents demonstrate contemporaneous concern about the failure by clinicians to report cases of post-transfusion hepatitis as well as the overall under-reporting of cases.<sup>1216</sup>

Some of the issues encountered during the Hepatitis C national lookback from April 1995 are also found in the earliest historical jaundice investigations. Examples can be seen of donors not engaging with correspondence,<sup>1217</sup> donors moving house,<sup>1218</sup> and of missing batch numbers making investigations challenging.<sup>1219</sup>

During the 1960s and 1970s, the time and effort required for a successful lookback exercise were highlighted by some clinicians.<sup>1220</sup> The need for greater staff resource and more resources generally was frequently emphasised.<sup>1221</sup>

Despite ad hoc historical jaundice investigations from the 1940s onwards, there was no formal system of lookback for hepatitis cases. The first formal lookback programme in the UK began in October 1985: this was in respect of HIV.<sup>1222</sup>

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1213 *Homologous serum jaundice* The Lancet 16 January 1943 p6 NHBT0000091\_011

1214 Blood-borne

1215 Minutes of Regional Blood Transfusion Officers meeting 14 January 1948 pp1-2 DHSC0100054. Dr Maycock was consultant adviser on blood transfusion to the Ministry of Health from 1946 to 1978. An example of a form completed at the RTC in Cardiff in 1949 is Suspected cases of homologous serum jaundice 26 October 1949 DHSC0100011\_006

1216 See for example Letter from a regional transfusion officer to Dr Maycock 1 December 1947 p2 DHSC0100009\_103

1217 Suspected cases of homologous serum jaundice 15 August 1950 DHSC0100011\_011

1218 Letter from Dr B Stone to Dr Maycock 13 June 1969 DHSC0100113\_017

1219 Suspected cases of homologous serum jaundice 26 October 1949 DHSC0100011\_006

1220 See for example letter from Dr Drummond, the director of the Cardiff RTC, Letter from Dr R Drummond to Dr Maycock 22 May 1962 DHSC0100015\_241

1221 See for example the comments about staff shortages at the regional transfusion directors’ meeting on 22 February 1978: Minutes of Regional Transfusion Directors meeting 22 February 1978 p7 NHBT0018353

1222 See the chapter on *HIV Lookback*.



## Consideration of a national Hepatitis C lookback prior to the introduction of Hepatitis C screening

From 1988 when Hepatitis C was first cloned and became identifiable, and it was apparent that a test was likely to follow soon, to September 1991 when Hepatitis C screening of blood was introduced, the topic of a national Hepatitis C lookback was regularly raised, mooted and deferred within national committees. Yet by the time screening was finally introduced, no formal lookback was launched alongside it.

### Consideration in 1989

A test was available from May 1989, though for reasons explored in the chapter on *Hepatitis C Screening* was not put into use as a screening test in the UK. Consideration of whether to introduce a surrogate test was continuing. On 9 June 1989, during a meeting about the national study on surrogate Hepatitis C markers in blood donors, it was agreed there would be no attempt to follow up on the recipients of surrogate marker positive donations because of the “*enormous effort involved and lack of cost effectiveness*”. This was notwithstanding the fact that “*valuable scientific information might be derived*” from a lookback. The conclusion was that a lookback would be a separate study requiring ethical permission and funding.<sup>1223</sup>

In late 1989 Dr Harold Gunson undertook a pilot study to assess the introduction of routine anti-Hepatitis C tests in RTCs.<sup>1224</sup> Two surrogate markers were already in use in the US and the purpose of the study was to “*assess the effect of introducing similar tests in this country*”.<sup>1225</sup> Three regions were selected.<sup>1226</sup>

Approximately 20 donors from the Manchester region were found to be positive when stored serum from this study was tested using early Hepatitis C test kits. Dr Douglas Lee, of the Manchester (North Western) RTC, wrote to the legal advisor of the North Western Regional Health Authority for advice. He said that “*we will be taking steps in due course to withdraw them from our donor panels and provide appropriate counselling.*” He noted that one or more donations from each of these infected donors had been issued to patients: “*It would be very valuable to undertake a ‘look back exercise’ and to examine surviving recipients of their blood for their Hepatitis C status.*” However, Dr Lee also raised concerns about being exposed to litigation by placing “*the relevant information before the patient in order to obtain their consent to give a sample.*” In his view giving the patient information that he or she had potentially received infected blood would give them “*the necessary ammunition to take action against us on the grounds of product liability.*”<sup>1227</sup> In his letter, no

1223 Minutes of meeting on national study on surrogate NANBH markers in blood donors 9 June 1989 p3 NHBT0000076\_037

1224 Draft protocol to the pilot study to assess the introduction of routine HCV-tests in RTCs 8 November 1989 JPAC0000042\_048

1225 Letter from Dr Douglas Lee to Eric Jones 11 October 1989 NHBT0086417\_021

1226 West Midlands, North-East Thames and Trent. Draft protocol to the pilot study to assess the introduction of routine HCV-tests in RTCs p1 JPAC0000042\_048

1227 Letter from Dr Lee to Eric Jones 11 October 1989 NHBT0086417\_021

mention is made of the value of informing those who received the blood of the possibility of infection. The regional legal adviser agreed with Dr Lee's concerns and questioned whether the "*comparative benefit is outweighed by that risk*" of the cost of a patient pursuing legal action.<sup>1228</sup> By way of comment, no professional who has information that, in the course of the services they have provided, their client or patient may have been harmed should regard their self-interest or the interests of the professional group to which they belong as a reason not to tell their client or patient that they may have been failed either by that professional or by the professional group. The professional's primary duty is to serve the best interests of their client or patient, even if those may harm their own. This advice does not stand scrutiny on the basis it was given.

### Consideration in 1990

The focus in late 1989 and early 1990 was initially on counselling donors who were found to be anti-Hepatitis C positive.<sup>1229</sup> The Advisory Committee on the Virological Safety of Blood ("ACVSB")'s concern on 24 April 1990 mirrors their later concern about lookback: that there would be "*problems of counselling donors in view of the state of knowledge about the significance of a positive reaction to the test.*"<sup>1230</sup> The key focus of the discussion was the need to have more information about what a positive result on the various Hepatitis C antibody tests meant.

The discussion moved on to address the use of Hepatitis C screening in reverse lookbacks, that is where a patient presented with signs and symptoms of Hepatitis C and an investigation was undertaken to identify whether the patient had received blood or blood products, and if so from whom. On 1 May 1990 Professor John Cash wrote to Dr Gunson raising the issue, in the "*twilight period*" before anti-Hepatitis C screening, of a lookback for positive donations. He asked: "*should we not be doing anti-HCV tests on the relevant donation aliquots so that we can more readily locate 'the offending donor' with a view to taking him/her off the panel.*"<sup>1231</sup>

This issue was also raised by Dr Ruthven Mitchell in a letter to Professor Cash on 14 May 1990: "*Where alleged non-A, non-B transmission has occurred and is notified to the Regional Transfusion Centres, the problem is, should the BTS [Blood Transfusion Service] have a*

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1228 Letter from Eric Jones to Dr Lee 22 February 1990 NHBT0086417\_016

1229 ie those testing positive had antibodies to Hepatitis C, which might indicate that they had had or currently had such an infection. Professor John Cash asked Dr Jack Gillon, who was responsible for care and selection of blood donors for the South East Scotland Blood Transfusion Service, in a letter of 21 June 1990, to chair a small group to produce a first draft of guidelines for counselling donors and onward referral to specialist clinical teams. Letter from Professor John Cash to Dr Gillon 21 June 1990 PRSE0004689. See also Minutes of UK Advisory Committee on Transfusion Transmitted Diseases ("ACTTD") meeting 9 October 1989 p3 NHBT0000043\_034, Minutes of UK ACTTD meeting 22 November 1989 p6 NHBT0000043\_039, Minutes of UK ACTTD meeting 16 March 1990 pp2-3 NHBT0000043\_047

1230 Minutes of ACVSB meeting 24 April 1990 p2 NHBT0000072\_098

1231 Letter from Professor Cash to Dr Gunson 1 May 1990 PRSE0000218. Professor Cash was the National Medical and Scientific Director of the SNBTS. Dr Gunson was the Director of the National Directorate for the NBTS and consultant adviser in blood transfusion to the CMO.

*look-back policy so as to identify donors who may have transmitted the disease or should we not?" Dr Mitchell referred to a recent oral discussion with Professor Cash and to having mentioned it at the ACVSB meeting on 24 April and recorded that the decision was "at the present time that we have no look-back policy, although you will understand that in doing so, the Service could be considered to be negligent in not advising about potential future use of donor blood."<sup>1232</sup>*

Dr Gunson wrote to Professor Cash on 21 May 1990 and said that he was not sure that RTCs would have access to anti-Hepatitis C test material. His view was that it "*may be worthwhile to carry out the usual investigations when a transfusion-associated NANBH case is reported and to ensure that a library sample of serum is retained from each donor seen. Perhaps we could discuss this in June.*"<sup>1233</sup>

On 27 June 1990 this discussion occurred when the National Blood Transfusion Service ("NBTS") and Scottish National Blood Transfusion Service ("SNBTS") liaison committee met. One of the issues it considered was whether there should be a Hepatitis C lookback programme. The conclusion was that "*whilst tests and policies are evolving it would not be appropriate to establish a lookback policy and that ACVSB should take a view in due course.*" It was however noted that France had a "*comprehensive*" lookback programme.<sup>1234</sup>

The next ACVSB meeting occurred on 2 July 1990. It was agreed there that a recommendation should be made to ministers to introduce Hepatitis C screening for UK blood donors – but consideration of the question of a Hepatitis C lookback procedure was postponed.<sup>1235</sup> The chairman, Dr Jeremy Metters, did however conclude that blood found to be positive in the pilot study should not be used, although no look should be taken at whether recipients of positive donations (or of previous donations from positive donors) had suffered infection.<sup>1236</sup>

Dr Gunson's view was repeated in correspondence sent by Professor Cash to Scottish regional transfusion directors on 9 July 1990: "*we both agreed [that] ... it would not, after we start anti-HCV donation screening, be appropriate to introduce a systematic look-back programme on previous recipient – as was done for HIV-1.*" Dr Gunson and Professor Cash did consider it appropriate to examine the Hepatitis C status of donors implicated in a case of reported post-transfusion hepatitis in the period before routine anti-Hepatitis C donation screening commenced.<sup>1237</sup>

On 3 October 1990 Professor Cash wrote to Dr Gunson about continuing their "*efforts at harmonisation*" prior to an upcoming meeting of the SNBTS directors. Professor Cash

1232 Letter from Dr Mitchell to Professor Cash 14 May 1990 NHBT0000189\_131. Dr Mitchell was director of the Glasgow and the West of Scotland BTS.

1233 Letter from Dr Gunson to Professor Cash 21 May 1990 PRSE0004033

1234 Minutes of NBTS and SNBTS Liaison Committee meeting 27 June 1990 p2 NHBT0000189\_173

1235 Minutes of ACVSB meeting 2 July 1990 p3 PRSE0000976. The ACVSB concluded that a pilot study using two different tests should first be undertaken so as to decide which was the best: see the chapter on *Hepatitis C Screening*.

1236 Minutes of ACVSB meeting 2 July 1990 pp3-4 PRSE0000976

1237 Letter from Professor Cash to Dr William Withrow and others 9 July 1990 p1 PRSE0001133. Emphasis in the original.

sought Dr Gunson’s view on lookback: *“You will have noted that our team have indicated the need for a policy statement and in their view ‘look-back’ should be attempted.”*<sup>1238</sup>

The Scottish directors pressed their view. At the meeting of the SNBTS directors, which took place in November 1990, it was agreed that Professor Cash would write to the ACVSB asking that *“careful consideration”* be given to introducing a Hepatitis C lookback.<sup>1239</sup> He did so on 22 November 1990.<sup>1240</sup> The ACVSB had already met the day before and noted that the Advisory Committee on Transfusion Transmitted Diseases (“ACTTD”) would be meeting to discuss the issue of counselling positive donors, and would consider the issue of lookback.<sup>1241</sup> The issue thus remained in the pending tray, having been passed from one body to another.

The day after Professor Cash wrote to the ACVSB, Dr Jack Gillon (in Scotland) produced a standardised procedure for managing Hepatitis C positive donors. As part of this procedure he recommended that where a regular blood donor was confirmed as Hepatitis C positive *“the fate of previous donations is determined and ‘lookback’ initiated in accordance with SNBTS policy.”*<sup>1242</sup>

In the absence of a national lookback policy and funding for this from central government, some individual directors who considered lookback important explored other avenues for funding this in their own region. Dr (later Professor) Marcela Contreras at the North London RTC considered that an application should be made *“as soon as possible”* to the Medical Research Council and/or the Wellcome Foundation for funding in order to undertake a lookback for recipients of blood *“who are now confirmed positive for HCV antibodies.”* She also suggested applying for a grant from the Research Fund of the Regional Health Authority.<sup>1243</sup>

## Consideration in 1991

On 8 January 1991 the ACTTD met. It was agreed that there may be *“an ethical obligation to inform patients who may have received transfusions in the past from anti-HCV positive donations. This will involve considerable additional work including testing of library samples*

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1238 Letter from Professor Cash to Dr Gunson 3 October 1990 p2 NHBT0000073\_007. Dr Gunson replied on 26 November 1990. Letter from Dr Gunson to Professor Cash 26 November 1990 PRSE0002167

1239 Minutes of SNBTS Medical and Scientific Committee meeting 6 November 1990 p7 PRSE0000348

1240 Letter from Professor Cash to Dr Metters 22 November 1990 PRSE0001573. He wrote to Dr Metters, Deputy Chief Medical Officer of England and chair of the ACVSB, requesting that a lookback be undertaken. Dr Metters’ response on 14 January 1991 confirmed that the topic had been discussed at the ACVSB meeting on 21 November and the next ACVSB meeting was due to take place on 25 February 1991. Letter from Dr Metters to Professor Cash 14 January 1991 SBTS0000009\_005

1241 Minutes of ACVSB meeting 21 November 1990 p4 NHBT0000073\_018. Dr Gunson updated Professor Cash to this effect on 26 November 1990. Letter from Dr Gunson to Professor Cash 26 November 1990 PRSE0002167

1242 Recommended procedure for the management of Anti-HCV positive donors 23 November 1990 p2 PRSE0000515. This paper was discussed at the 8 January 1991 meeting of ACTTD. Minutes of UK ACTTD meeting 8 January 1991 p3 NHBT0000073\_028

1243 Memo from Dr Contreras to Dr Thomson and Dr Mary Brennan 17 December 1990 NHBT0000052\_003

*and will have to be funded. Extension of this to epidemiological investigations should be the subject of separate research studies.*<sup>1244</sup>

Although it had now (and somewhat obviously) been decided by at least one influential advisory body that there was an ethical obligation to tell patients who might have received positive donations in the past, no decision to take the action needed to identify who they were (a lookback) was actually taken. By way of comment, the effort and expense needed seemed to trump the ethical obligation to do it.

Nevertheless, some reverse lookback work continued.<sup>1245</sup>

On 19 February 1991, the SNBTS Medical and Scientific Committee met. It was recorded that *“in the light of national events, it was agreed no ‘Look Back’ should be introduced at present.”*<sup>1246</sup> No further context is given as to what national events were being referred to, but this may be a reference to the Gulf War; it may also be a reference to the indecision in England and Wales, and hence in the UK as a whole.<sup>1247</sup>

On 25 February 1991 the ACVSB met again. It *“discussed the problems of look-back and recommended that it should not be undertaken as a service, leaving the option for those carrying out research. However, all cases of post-transfusion hepatitis should continue to be investigated.”*<sup>1248</sup> In other words, reverse lookback continued – identifying donors where a patient presented with hepatitis – but not targeted lookback where recipients were traced after a positive donation was identified.

### **A dispute about recommending lookback: SNBTS**

In March 1991 Professor Cash wrote to Dr Gillon informing him that the SNBTS Medical and Scientific Committee endorsed his document on Hepatitis C counselling to be used nationally as guidelines in leaflet form, but also expressly asking him to remove one of the questions about lookback *“in the light of national events with regard to the implementation of ‘Look-back’”*.<sup>1249</sup> Dr Gillon states that the decision *“came out of the blue”* and even today,

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1244 Minutes of UK ACTTD meeting 8 January 1991 p4 NHBT0000073\_028

1245 For example, on 11 February 1991 Dr Vanessa Martlew contacted Dr David Edwards, consultant haematologist at the Glan Clwyd Hospital, as part of an investigation into a patient’s jaundice. The investigations showed that the donors were negative for markers of Hepatitis B and Hepatitis C and therefore Dr Martlew considered that it was unlikely the patient’s jaundice was attributable to a blood transfusion. Letter from Dr Vanessa Martlew to Dr David Edwards 11 February 1991 NHBT0076930\_004. She was responding to a letter from Dr Edwards on 3 December 1990: Letter from Dr Edwards to Dr Martlew 3 December 1990 NHBT0076930\_015

1246 Minutes of SNBTS Medical and Scientific Committee meeting 19 February 1991 p4 PRSE0003568

1247 See for example Professor Cash’s letter about the impact of the Gulf conflict: Letter from Professor Cash to Dr Gunson 24 January 1991 NHBT0000073\_033

1248 Minutes of ACVSB meeting 25 February 1991 p6 PRSE0002280

1249 Letter from Professor Cash to Dr Gillon 12 March 1991 PRSE0004416. The question and its answer were *“What about my previous donations? The recipients of previous donations will be traced and their Consultants or GP’s informed. We hope to obtain results of any tests carried out. However, it may cause distress to the donor to discuss this matter in any detail. A general comment suggesting that we are going to check to see that the recipients are alright, that they get any treatment they may require, should be sufficient.”* Recommended procedure for the management of Anti-HCV positive donors p12 PRSE0000515



*“I still have no idea”* what those national events were. Dr Brian McClelland had also been unable to enlighten him.<sup>1250</sup>

Dr Gillon has told the Inquiry that he found this position *“entirely unacceptable”*. He decided that he would not accept that he should *“resile from what I regarded as my professional responsibility to the recipients of previous donations from donors likely to have been infectious at the time.”* Dr Gillon noted that serum samples existed from as far back as 1984 and it was his *“routine practice to extract and test these samples”* in order to determine a sample’s infective status. Dr Gillon concluded it would be *“unethical to fail to act”* and that he owed a duty of care to the recipient of any blood or blood products.<sup>1251</sup> He expanded on this in oral evidence when he explained:

*“The main thing I think is for the individual recipient in terms of disclosing to them that they have a condition which is potentially serious, and although there is no available treatment, it’s something that is certainly worth looking further into and getting expert professional advice and follow-up. In the event that treatment did become available then they would be known about, they would be first in line for treatment. And the second consideration was that if we didn’t tell them, they might then pass on it to others, particularly sexual contacts, obviously. And it seemed to me that that, combined with the fact that we had accepted across the western world that that’s what we should do when we introduced HIV screening, there was no logic in saying that we shouldn’t do the same for hepatitis C patients.”*<sup>1252</sup>

Dr Patricia Hewitt echoed similar views. Asked why a lookback was not organised until 1995 she responded:

*“I always understood that that was a decision made by the Department of Health and my understanding was that part of the justification for that was that there was no treatment available for hepatitis C, so one would be seeking out individuals, establishing whether or not they had been infected with hepatitis C but then having nothing in the form of treatment to offer them. I found that very strange because, of course, the same could have been said for HIV in 1985. When we started screening donations for HIV, there was no treatment available for HIV infection, so I felt that that didn’t appear logical”*.

She added that there seemed to be a lot of concern that:

*“seeking out individuals and telling them they had had hepatitis C, when there was no treatment available, was putting an unnecessary burden on them and, unlike HIV, there was no clear evidence for easy spread to other people, in particular sexual partners. But I still struggle with that because I am sure that in 1991, when we started screening blood donations for hepatitis C, I mean we*

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1250 Dr Jack Gillon Transcript 19 January 2022 pp102-103 INQY1000173

1251 Written Statement of Dr Jack Gillon paras 250-251 WITN6987001

1252 Dr Jack Gillon Transcript 19 January 2022 pp104-105 INQY1000173

*knew there was no treatment available and we told our donors that, but we did say to them that there is one thing you could do which might be of help, because this could cause you problems in the future and we would advise you to limit your alcohol intake because that could be a factor in making liver disease more likely or worse. So there was something that could have been offered. I know it is quite a burden to people to tell them you have got this infection, there is no treatment for it and, actually, you have to give up alcohol, but there was something that could have been done to try and minimise the effect, and I don't see that in the discussions".*<sup>1253</sup>

Dr Gillon discussed his view with Dr Brian McClelland, who accepted Dr Gillon's position and told Dr Gillon he would discuss this issue with Professor Cash. Dr Gillon was then allowed to undertake a Hepatitis C lookback if he described it as a "*pilot study*" and published the results.<sup>1254</sup> Dr Gillon agreed. He and Dr Yasmin Ayob undertook a Hepatitis C lookback study between 1 September 1991 and 29 February 1992. Dr Gillon has told the Inquiry that he continued with this lookback after 29 February 1992, as he always intended to do so since no required end date had been suggested to him in his prior discussions.<sup>1255</sup> From his perspective, "*The, in inverted commas, 'pilot study' continued, because of course it wasn't a pilot study, it was standard practice as far as I was concerned.*"<sup>1256</sup>

### **Resistance to "a study" before the introduction of universal Hepatitis C screening**

On 17 June 1991 Professor Cash again wrote to Dr Gunson about lookback and suggested that Dr Gunson write to Professor Jean-Pierre Allain "*to see, among other things, if he will establish a UK BTS [Blood Transfusion Service] prospective and look-back study as soon as possible. I'm keen to lock an SNBTS team into the programme and time is short!*"<sup>1257</sup> Dr Gunson spoke to Professor Allain who agreed to provide a protocol for a prospective lookback study.<sup>1258</sup> As part of this proposal Professor Allain supported identifying and approaching all recipients of blood that was "*screen positive (repeat reactive)*".<sup>1259</sup>

However, this proposed study was not popular with some regional transfusion directors. Dr Jean Harrison of North East Thames RTC declined to participate on the basis she considered it to be unethical because a patient would ask whether screening of blood had been available earlier resulting in "*possible medico-legal implications.*"<sup>1260</sup> Her view was that the study was also "*too late*" because samples should have been stored for the years before

1253 Dr Patricia Hewitt Transcript 10 December 2021 pp5-6 INQY1000171

1254 Written Statement of Dr Jack Gillon para 252 WITN6987001

1255 Dr Yasmin Ayob was the deputy director of the Kuala Lumpur BTS who was attached to the South East Blood Transfusion Centre for a year. Written Statement of Dr Jack Gillon paras 253-4 WITN6987001

1256 Dr Jack Gillon Transcript 19 January 2022 p106 INQY1000173

1257 Letter from Professor Cash to Dr Gunson 17 June 1991 p2 NHBT0000192\_091. Professor Allain was the East Anglia regional transfusion director.

1258 Letter from Dr Gunson to Professor Cash 20 June 1991 p2 NHBT0000192\_095

1259 Fax from Dr Allain to Dr Gunson 26 June 1991 p1 NHBT0000050\_016

1260 It is difficult to understand why this should cause ethical difficulty. The reasoning is self-protective rather than giving priority to the patient's rights. In short, the ethics applied here are the wrong way

screening was introduced and then retrospectively tested.<sup>1261</sup> Dr Contreras of the North London RTC said there was insufficient time to obtain ethical approval at each hospital and the North London RTC was conducting its own prospective study, but that they would add data to Professor Allain’s study if they received ethical approval.<sup>1262</sup>

Concerns were expressed in Scotland as well as south of the border. In July 1991 Dr McIntyre of the Scottish Home and Health Department (“SHHD”) wrote: *“In the present state of knowledge, donors who are only HCV seropositive donors without evidence of antigen may not be infectious. What purpose is to be served by going back. Will it cause the recipient of the blood (the 50% who are still alive after 2 years) unnecessary worry and possibly distress. In certain circumstances it could also give rise to litigation and it may be that you would wish to discuss this particular point with our Solicitors before this policy is put into effect.”*<sup>1263</sup>

There was further indication of wavering views immediately prior to the introduction of universal screening. When the ACTTD met in mid August its discussion focused on the imminent introduction of Hepatitis C blood screening. However, under “Any Other Business” Dr John Barbara raised the issue of lookback on behalf of Dr Hewitt. It was noted that the matter had been discussed by the Committee in the past but that the Committee’s minutes did not indicate that any decision had been made; and also that *“It has not been considered either, as far as can be determined, by ACVSB.”* The Committee agreed that: *“look-back may have legal implications and that **the matter should be considered**. Look-back, at least to a point in time when it could be stated that a satisfactory test was available, may be advisable.”*<sup>1264</sup>

During a discussion about the introduction of donor counselling at a meeting of the SNBTS Medical and Scientific Committee on 14 and 15 August 1991, Dr Stan Urbaniak asked what should be said to a Hepatitis C positive donor who asked about his previous donations. It was noted that it had previously been agreed that there would be no lookback *“and this should be conveyed to the donor.”* It was noted *“that this matter might be reconsidered by the ACTTD.”* However, the extent of the SNBTS Committee’s agreement was that the only person to be informed was the donor’s GP.<sup>1265</sup>

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round. If a patient had been dealt with in a way which might entitle them to take legal action they should have been told this, and there was no good reason to hide it.

1261 Letter from Dr Harrison to Professor Allain 1 July 1991 NHBT0000075\_003

1262 Letter from Dr Contreras to Professor Allain 3 July 1991 NHBT0000075\_009

1263 Note from Dr McIntyre to Rab Panton 10 July 1991 p2 SCGV0000163\_043. The reference to 50% is to recognise that many patients who require transfusions do so for a serious underlying condition which can be fatal: the statistical evidence available at the time suggested that this was true of roughly half of the cohort of transfusion recipients.

1264 Minutes of UK ACTTD meeting 13 August 1991 p6 NHBT0000062\_096. Emphasis added. This comment sums up much of what had (not) happened in the main advisory bodies in the previous three years.

1265 Dr Urbaniak was the regional transfusion director for Aberdeen and North East Scotland. Minutes of SNBTS Medical and Scientific Committee meeting 14 and 15 August 1991 p17 SBTS0000445\_003. This agreement seems to have missed the point, which is that the donor was concerned about whether they may have unwittingly caused infection in unknown recipients. How could his GP help resolve that question?

The above chronology demonstrates that views on whether there should be a Hepatitis C lookback, and if so what form it should take, and whether it should be co-ordinated nationally or left to individual initiatives fluctuated through a multitude of committee meetings in the late 1980s and early 1990s. In summary, the key dates look to be:

- July 1990: ACVSB postpones decision
- November 1990: ACVSB is told that the ACTTD will consider the issue, and takes no decision of its own (the Scots separately ask that “*careful consideration*” be given to implementing lookback)
- August 1991: ACTTD decides lookback should be considered

By way of comment, nothing seems to have been settled about funding, perhaps because a first step in securing funding was identifying more precisely what exactly was to be funded; though identifying what funding might be available itself might determine what was to be proposed. The dangers of going round in circles were all too obvious.

As a consequence, in contrast with the position in respect of HIV, no lookback was introduced contemporaneously with the start of universal screening.

## Consideration of a national Hepatitis C lookback following the introduction of Hepatitis C screening

From 1 September 1991 blood donations in the UK were screened for Hepatitis C.<sup>1266</sup>

Many individuals working in UK blood services assumed that a Hepatitis C lookback would take place alongside or after the introduction of Hepatitis C screening, in a process similar to that for the HIV lookback.<sup>1267</sup> This did not happen. Dr Angela Robinson, medical director of the National Blood Authority (“NBA”) from 1994 to 2005, told the Inquiry that she had always understood the decision not to carry out a Hepatitis C lookback was that of the Department of Health.<sup>1268</sup> Dr Hewitt told the Inquiry that a “*central directive from the Department of Health*” was required and without such a directive, 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.*”<sup>1269</sup>

Between September 1991 and November 1993 the issue of a lookback could have been discussed at meetings of various bodies, but it was not.<sup>1270</sup>

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1266 See the chapter on *Hepatitis C Screening*.

1267 Written Statement of Dr Angela Robinson para 41 WITN6926003, Written Statement of Dr Patricia Hewitt para 293 WITN3101006

1268 Written Statement of Dr Angela Robinson para 41 WITN6926003

1269 Written Statement of Dr Patricia Hewitt para 293 WITN3101006

1270 These meetings were: (a) ACTTD (13 September 1991), for which it was on the agenda but not discussed. Agenda for UK ACTTD meeting 13 September 1991 NHBT0000044\_046, Minutes of UK ACTTD meeting 13 September 1991 NHBT0000075\_054 (b) ACVSB, which was told there had been no decision on a lookback study. Minutes of ACVSB meeting 29 October 1991 p2 NHBT0000079\_004,

On 18 November 1993, however, Professor Cash again raised the introduction of a Hepatitis C lookback. In a letter to Dr Gunson he suggested that the issue might be discussed by the Advisory Committee on the Microbiological Safety of Blood and Tissue for Transplantation (“MSBT”), which had replaced the ACVSB. He stated that at a symposium on Hepatitis C in Edinburgh a *“distinguished speaker indicated that efforts ought to be made by the transfusion services, in the first instance, to track patients who had received blood and blood components.”* This was on the basis that *“some of these patients could benefit substantially from some modern therapeutic manoeuvre and that we had a duty to ensure this option was made available.”*<sup>1271</sup> This is one of the first instances of the need for a Hepatitis C lookback being advocated on the basis of patient benefit.

Professor Cash had discussed this at the SNBTS Medical and Scientific Committee and *“while it received support colleagues stepped back from introducing a look-back policy until such times as further (UK) deliberations had taken place.”*<sup>1272</sup>

During this period ad hoc Hepatitis C lookbacks were continuing to take place. For example, Dr George Galea has told the Inquiry that in Inverness if a donor was found who had later tested positive for Hepatitis C, they would look back and see whether the blood taken was still in stock, whether it was transfused or sent to PFC.<sup>1273</sup>

What was happening as well, almost (as it were) in the background, was that Dr Gillon was continuing with his so-called “pilot” study, conducting a lookback in Edinburgh and the South East of Scotland BTS. By November 1993 he was in a position, with his colleagues, to submit a report for publication which showed that in the first six months of routine testing 20 sero-positive donors (of whom 15 were regular donors) had been confirmed to be sero-positive.<sup>1274</sup>

## 1994

The question of lookback for recipients of blood from donors subsequently shown to be Hepatitis C positive was finally raised, after more than two years, at the Standing Advisory Committee on Transfusion Transmitted Infections (“SACTTI”)<sup>1275</sup> when it met in January 1994. The committee was supportive of seeking a research grant *“for [the] potentially clinically beneficial undertaking”* of considering the value of treatment by interferon and

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(c) ACTTD Minutes of UK ACTTD meeting 6 December 1991 NHBT0000044\_057. No meetings in 1992 considered lookback; nor did any before the autumn of 1993.

1271 Letter from Professor Cash to Dr Gunson 18 November 1993 PRSE0003928

1272 Letter from Professor Cash to Dr Gunson 18 November 1993 PRSE0003928

1273 Dr George Galea Transcript 7 December 2021 pp116-117 INQY1000168

1274 Ayob et al *Risk of hepatitis C in patients who received blood from donors subsequently shown to be carriers of hepatitis C virus* Transfusion Medicine December 1994 p1 PRSE0001046. The account of this is picked up in the chronological account at July 1994, when the report was accepted for publication.

1275 SACTTI was the successor committee to ACTTD. Minutes of UK BTS/National Institute for Biological Standards & Control (“NIBSC”) Standing Advisory Committee on Transfusion Transmitted Infections meeting 11 October 1993 p1 NHBT0007465



ribavirin, which Dr Geoffrey Dusheiko in particular advocated.<sup>1276</sup> The implication of this is that if it was shown that there was now treatment which might be effective, there would be very powerful reasons for instituting lookback. Infected recipients and infective donors could both be offered some treatment.

However, when the same committee met in April 1994 it acknowledged that there were “*Conflicting impressions*” on the (clinical) effectiveness of antiviral treatment. The “*cost-effectiveness*” of these treatments was also discussed. The “*value*” of a lookback and the question of who would be responsible for such a lookback and for subsequent patient management were said to be “*difficult to assess.*” The committee noted that “*the issue needs resolution and will be examined in more detail by a group to be convened to consider it further.*”<sup>1277</sup>

In May 1994, Dr Gillon briefed the SNBTS Medical and Scientific Committee. The issue was described as “*very complex and extremely important*”. Dr (later Professor) Aileen Keel, a senior medical officer in the SHHD, expressed the view that the SHHD “*may not have a locus in this matter*” and “*that the SNBTS should make a decision on lookback for HCV that was based on their professional judgement.*” However, before SNBTS took any action she asked to be given the opportunity to discuss the issues with SHHD colleagues to seek their views and that SNBTS should take no formal action before she had reported them back to Professor Cash. Subject to that, the meeting agreed that where a regular donor was found to be anti-HCV positive, previous samples of their donations which had been archived should be tested; clinicians to whom blood components from that donor had been sent should be notified; recipients identified, and the medical officer responsible for administering the components should be given advice concerning the infection risk and the recommended action. Dr Keel agreed that if the SHHD agreed that SNBTS should develop and implement such a lookback policy for HCV, she would communicate this to the Department of Health.<sup>1278</sup>

Then, in December 1994 Dr Gillon’s report on the results from the first six months of his pilot study were published. Of 20 Hepatitis C positive donors, 15 were regular donors.<sup>1279</sup> There was little concern about false positives. All living recipients identified were Hepatitis C positive. Dr Gillon has told the Inquiry that “*there is no doubt*” that the publication of these results “*prompted the reversal of the policy not to carry out lookback in the UK.*”<sup>1280</sup> This study appears to have represented a turning point for many. For example, Dr Gillon’s briefing on his study in May 1994 caused Professor Keel to think that a national lookback

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1276 Minutes of UK BTS/NIBSC SACTTI meeting 18 January 1994 p5 NHBT0000088\_006. Professor Dusheiko had a large viral hepatitis outpatient clinic at the Royal Free. Written Statement of Professor Geoffrey Dusheiko para 2.31 WITN3754048

1277 Minutes of the UK BTS/NIBSC SACTTI meeting 19 April 1994 pp2-3 PRSE0000986. A plan was made for Professor Richard Tedder and Dr Fereydoun Ala to review the data on the effectiveness of antiviral treatment.

1278 Minutes of SNBTS Medical and Scientific Committee meeting 18 May 1994 pp5-6 PRSE0003685

1279 Ayob et al *Risk of hepatitis C in patients who received blood from donors subsequently shown to be carriers of hepatitis C virus* Transfusion Medicine December 1994 PRSE0001046

1280 Written Statement of Dr Jack Gillon para 256 WITN6987001

was “feasible”. She told the Inquiry that it was from this point that she “immediately started to put the wheels in motion in terms of achieving an SHHD policy decision in this area.”<sup>1281</sup>

Though it was not until December that the results were published to the scientific world, the results were known some time prior to then.<sup>1282</sup> After the Medical and Scientific Committee of SNBTS had formally recommended that a hepatitis lookback should be implemented “without delay”, following its May meeting discussed above, David McIntosh, general manager of SNBTS, sent a memo to the SHHD notifying them that SNBTS proposed to start a Hepatitis C lookback on 1 June 1994. The rationale for this immediate decision was: “the medical and scientific reasons for this, combined with good ethical and legal arguments, as well as the obvious public relations implications”. England, Wales and Northern Ireland were to receive “prior warning” of this Scottish lookback. The cost of this lookback was “not ... excessive” and if necessary would be met within existing SNBTS resources. However, there might be additional “knock-on costs”, such as those for treatment.<sup>1283</sup>

The impact of this Scottish push for a lookback was felt in the rest of the four nations. Dr Fereydoun Ala, Chairman of the NBS Advisory Committee on Transfusion Transmitted Infection, in a letter dated 20 July 1994, cited SNBTS as the advocates of Hepatitis C lookback. Professor Cash and Dr Richard Tedder were noted to be proponents of lookback. Unnamed others were “agnostic”.<sup>1284</sup>

On 5 August 1994 an ad hoc meeting of SACTTI was called to discuss the “desirability and feasibility” of a Hepatitis C lookback.<sup>1285</sup> Dr Robinson told the Inquiry that this meeting was “designed to prepare a case for presentation to DH [Department of Health] on the subject of HCV lookback”.<sup>1286</sup> Dr Gillon’s paper had been circulated in advance of the meeting.<sup>1287</sup> It was noted that there was “growing evidence that this is not a trivial virus, and that a significant proportion of patients benefit from receiving therapy.” The group concluded that NBTs had an “ethical responsibility” and there was a duty of care towards recipients of potentially infectious blood. The group agreed that “despite the current uncertainties regarding long-term efficacy of treatment, and its impact upon the natural history of hepatitis C, we have a moral obligation to inform and advise surviving potentially infected blood recipients.”<sup>1288</sup>

In September 1994 Professor Cash, on behalf of SACTTI, produced a paper for the MSBT on the merits of adopting a Hepatitis C lookback policy. It stated that a Hepatitis C lookback could be based on the current procedures of HIV lookback. It was estimated there would be

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1281 Written Statement of Professor Aileen Keel p20 WITN5736003

1282 They had been available since at least the 25 November 1993 (when the manuscript was accepted for publication) if not before.

1283 Fax from David McIntosh to Rab Panton 19 May 1994 p2 PRSE0002093

1284 Letter from Dr Ala to Dr Elwyn Elias 20 July 1994 NHBT0095526\_0026

1285 Minutes of Ad Hoc Assembly to Consider the Merits of an HCV “Look-Back” Policy 5 August 1994 NHBT0009383

1286 Written Statement of Dr Angela Robinson para 44 WITN6926003

1287 Ayob et al *Risk of hepatitis C in patients who received blood from donors of subsequently shown to be carriers of hepatitis C virus* Transfusion Medicine December 1994 PRSE0001046

1288 Minutes of Ad Hoc Assembly to Consider the Merits of an HCV “Look-Back” Policy 5 August 1994 pp3-4 NHBT0009383

around 3,000 cases for England and Wales. SACTTI's view was that there was "a serious case" for a Hepatitis C lookback and not to have one when an HIV lookback was previously undertaken "suggests double standards."<sup>1289</sup>

On 29 September 1994 the MSBT met. Dr Robinson presented the SACTTI paper. This prompted a discussion about available treatments. Professor Arie Zuckerman raised concerns that interferon was not licensed for treatment of Hepatitis C-related disease and ribavirin was noted to be "even more costly." He said that there was "considerable potential for litigation associated with HCV lookback." He considered there to be a "strong argument" for lookback for younger recipients of blood transfusion and that these patients showed a "good response rate if treated early."<sup>1290</sup>

George Tucker, of the SHHD, said that "approaches to institute HCV lookback in Scotland had been resisted, and it was important that a UK wide approach was adopted." Drs Alain George and Glenda Mock said that the Welsh Office and DHSS Northern Ireland supported a UK-wide approach.<sup>1291</sup> Members were asked to submit written comments for consideration at the next meeting. These written comments were overall in favour of instituting a lookback programme on the basis of a UK-wide approach and urged that consideration be given to the ethical and legal implications of contacting recipients of Hepatitis C-infected blood.<sup>1292</sup>

On 19 October 1994 SACTTI met. It was noted that MSBT had "several reservations" about the SACTTI recommendations for a lookback. MSBT was to convene a group of Dr Robinson, Dr Gorst and Professor Zuckerman to examine the implications of lookback "with special regard to younger patients." The following was recorded in the minutes:

*"Considerable discussion followed concerning the actual likely therapeutic benefits for those patients identified as infected and the cost-benefit vs the need for 'openness', the lack of which engendered much criticism with regard to HIV i.e. do the medical authorities have the right to decide whether patients should or should not know they have been infected, regardless of cost-benefit consideration, potential efficacy of therapy or age of recipients? A 'duty of care' was also perceived."*<sup>1293</sup>

The subcommittee duly met on 3 November 1994. The group noted the MSBT's comments on the September SACTTI paper. The MSBT had thought that current evidence suggested that a response rate of 60% for interferon was too high. It was more likely to be in the range of 20-40% with a risk of rebound once interferon was stopped. The long term outcome of interferon was "not yet established." Interferon had however since been licensed for treatment of Hepatitis C chronic liver damage. Concern was raised about giving interferon to patients

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1289 Recommendations of the Standing Advisory Committee on Transfusion Transmitted Infection to the MSBT Concerning the Merits of Adopting an HCV Look-Back Policy pp2-3 PRSE0001236

1290 Minutes of MSBT meeting 29 September 1994 pp3-4 PRSE0003670

1291 Minutes of MSBT meeting 29 September 1994 p4 PRSE0003670

1292 Draft Report from MSBT Subcommittee 15 December 1994 pp3-4 NHBT0005791

1293 Minutes of UKBTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (SCTTI) meeting 19 October 1994 p2 NHBT0010970

who were likely to have had an infection for at least five years (in light of the September 1991 screening date) as well as the expense of the drug. However, the subcommittee concluded: *“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.”* It estimated that 25% of recipients of infected blood *“may still be alive and traceable”*. The subcommittee noted that long term follow up studies *“have clearly demonstrated that transfusion transmitted hepatitis can no longer be regarded as a relatively benign disease.”* It was stated that *“transfusion transmitted HCV disease has serious implications for the younger transfused population”* and that a lookback programme would allow these patients to *“benefit from appropriate antiviral therapy being administered earlier in the course of their disease.”* A series of considerations were set out which mainly related to the legal implications of undertaking a Hepatitis C lookback programme, particularly as it was being commenced four to five years after the introduction of the screening programme.<sup>1294</sup>

On 10 November 1994 the Medical and Scientific Committee of SNBTS met. It was noted that the MSBT had *“some problems”* with the original Hepatitis C lookback proposals. A meeting between SNBTS and hepatologists in Edinburgh on lookback was described as producing *“very positive reactions and support for the programme had been received by clinicians.”* It was agreed that Scottish RTCs could start the lookback programme *“but only to the point, at this time, of gathering data sufficient to identify patients at risk.”*<sup>1295</sup>

On 16 November 1994 an article published in *The Independent* highlighted the growing concern about the hepatitis risk to people with haemophilia.<sup>1296</sup> This led to the Haemophilia Society publishing a press release.<sup>1297</sup> On the same day the *Evening Standard* reported that the UK Government was considering introducing a lookback, following the death of 12 people with haemophilia and concern about the risk to 3,000 patients who had received blood transfusions.<sup>1298</sup>

On 15 December 1994 the MSBT met and recommended that ministers should be advised to undertake a lookback programme to identify those patients at risk of Hepatitis C through NHS treatment. This was articulated on the basis of a duty of care towards those infected with Hepatitis C which required that *“procedures should be put in place to identify those patients at risk”* and *“Whatever is done should be done equally and uniformly throughout the UK.”*<sup>1299</sup> This was – after all that had passed – finally a decision to recommend lookback to ministers.

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1294 Draft Report from MSBT Subcommittee 15 December 1994 pp1-3 NHBT0005791

1295 Minutes of SNBTS Medical and Scientific Committee meeting 10 November 1994 pp4-5 STHB0000684

1296 The Independent *Disquiet grows over hepatitis risk to haemophiliacs* 16 November 1994 DHSC0004738\_131

1297 The Haemophilia Society Press Release *Hepatitis C Infection* 16 November 1994 HSOC0021550

1298 Evening Standard *Thousands at risk in diseased blood alert* 16 November 1994 DHSC0004738\_087. On the same day a briefing note was sent to the Prime Minister and Health Ministers. There was no reference to undertaking a Hepatitis C lookback within the briefing note. Memo from David Burrage to Jonathan Mogford and others DHSC0003527\_008, Briefing note for the Prime Minister on Hepatitis C 16 November 1994 DHSC0003527\_009, Note on drug reaction and medical treatments given in good faith DHSC0014961\_040

1299 Recommendation from MSBT to ministers 15 December 1994 DHSC0002552\_110



The minutes reveal that when Dr Robinson presented a report of the subcommittee's consideration on 3 November she gave more detailed figures: the best estimate was that 3,000 recipients were at risk of contracting transfusion transmitted Hepatitis C liver disease; that some 60-80% of recipients who developed Hepatitis C infection as a result would become carriers and 50% would develop chronic hepatitis. 20% might develop cirrhosis. Given "*the time span of events transfusion transmitted hepatitis C could have serious implications for the transfusion population ... transfusion recipients, some of whom may have been harmed, would benefit from a lookback exercise.*" She revealed, too, that four writs had been issued against the NBA, and its legal advice was a duty of care existed in this case; and that France and Ireland had invited anyone transfused before the previous five years to come forward for testing. The Chief Medical Officer ("CMO") was, exceptionally, in attendance at the meeting: he said that "*in the public interest an urgent decision on a UK wide basis was needed on the matters of principle. The detail was important, but less urgent.*" Dr Keel added that "*the view in Scotland was that the Secretary of State was vulnerable as look back was feasible since donors could be identified and traced, and advice from Scottish Office lawyers was that look back should start immediately.*"<sup>1300</sup>

By way of comment, these details, the scale of the infection that could be identified, and its consequences, show why a need for urgency was by now incontrovertible: and must make an observer wonder why it took so long, and why – quite apart from the moral and clinical imperatives to act – the fact of current litigation and the threat of more to come plainly also contributed to taking this decision.

A submission followed to Tom Sackville, the Parliamentary Under-Secretary of State for Health, on 16 December 1994, copied to the Private Office of the Secretary of State, Virginia Bottomley. It began by noting that: "*Media interest in hepatitis C continues. You will have received advice ... on Panorama's request for a Ministerial appearance on their programme scheduled for screening 9 January*" before setting out the advice that a lookback programme should begin. It was further noted that there were "*a number of loose ends*" including "*persuading the Scottish Office to stay with a UK-wide approach. They have been under pressure from their legal advisers to go ahead on their own.*"<sup>1301</sup>

Recognising that the advice of the MSBT was likely to leak, a "*Line to Take*" was advised so that ministers and officials would say the same thing. This read:

*"The MSBT will be making certain recommendations to the Secretaries of State of the four health departments concerning the identification and follow up of*

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1300 Minutes of MSBT meeting 15 December 1994 pp5-7 PRSE0003635

1301 Submission from Roger Scofield to the Parliamentary Under-Secretary of State for Health 16 December 1994 p1 DHSC0003544\_084. However officials within the Department of Health were alive to the fact that lookback was now actively under consideration. A minute from Roger Scofield on 9 December 1994 recorded that Hepatitis C had moved from being "*a problem on the horizon to a highly political and volatile policy issue*". Reference was made to the MSBT's meeting on 15 December, at which lookback would be considered, and Roger Scofield advised that "*Ministers will need to decide in the light of their advice, the cost of such a programme and the practical implications whether to give the go-ahead.*" Minute from Roger Scofield to Dr Metters and others 9 December 1994 p1, p3 DHSC0003512\_168



*people who may have been put at risk of HCV infection through NHS treatment. If Ministers decide to take action it is likely to be on a UK-wide basis and to require the drawing up of clear guidance on identification procedures and action to be taken.”*<sup>1302</sup>

On 22 December 1994 the Scottish Office wrote to SNBTS asking them to take forward “as expeditiously as possible” a Hepatitis C lookback for all of Scotland and to keep the SHHD informed.<sup>1303</sup> The Minister for Home Affairs and Health within the Scottish Office, Lord Peter Fraser, wrote on the same day to Tom Sackville, informing him that the advice which he had received from legal and medical staff “is such that I consider that it is no longer a matter of policy but of legal liability, and that the look-back should take place as soon as possible in Scotland.” He appreciated that there were “sensitivities” in proceeding in advance of the rest of the UK but considered that he had little choice but to take this forward. Referring to the fact that this might encourage further pressure for compensation, Lord Fraser added that “We shall not of course be publicising the look-back exercise and shall do all we can to avoid media interest. If, however, direct questions are asked, it would be difficult to avoid answering them.”<sup>1304</sup>

On 22 December 1994 a more detailed submission was sent to Tom Sackville about the UK Government’s response to Hepatitis C. Acknowledging that some 3,000 people were believed to have been infected by transfusion, and a further 3,000 people with haemophilia by their treatment, it noted the advice of departmental lawyers that:

*“Secretary of State may have a duty of care to do whatever can reasonably be done to identify, inform, counsel and treat any who may have become infected as a result of NHS treatment. This is not entirely clear; nor is it an absolute duty but in circumstance [sic] where:*

- *SofS acknowledges a broad responsibility for public health and the care of those in need of medical treatment;*
- *and is in the habit of issuing warnings concerning action to be taken to safeguard health and of seeking to identify those who are in particular danger of suffering ill health;*
- *and if there is action that can be taken to identify those who may be at risk;*
- *and having identified them there is action that could be taken to assist them;*
- *then if no such action is taken the SofS might have a case to answer.”*<sup>1305</sup>

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1302 Submission from Roger Scofield to the Parliamentary Under-Secretary of State for Health 16 December 1994 DHSC0003544\_084

1303 Letter from George Tucker to David McIntosh 22 December 1994 PRSE0000661

1304 Letter from Lord Fraser to Tom Sackville 22 December 1994 PRSE0001781. Lord Fraser copied the letter to ministers in the Welsh Office and Northern Ireland Office.

1305 Submission from Roger Scofield to the Parliamentary Under-Secretary of State for Health 22 December 1994 pp1-2 DHSC0032208\_149

By way of comment, this was wise advice: but the law was no different at the end of 1994 than it had been in September 1991 when universal screening of donations for HCV was introduced. It is therefore surprising that it had taken until now for it to be formally recorded for a minister, and that it had not, for instance, played more of a persuasive role in ensuring a much earlier lookback than it did. The inference is that it was the impact of media concern that led to the departmental lawyers being asked for advice upon what the legal position might be.

The submission noted that *“Until recently it was considered that lookback to identify recipients of blood transfusion who are at risk would be technically difficult; and as there was no effective treatment, to inform people they were at risk, when there was nothing that could be done about it, would increase distress without any benefit.”* It was noted that this position had now *“changed on both counts.”*<sup>1306</sup> The submission recorded:

*“There is now some confidence that many, but not all, recipients of blood infected with hepatitis C can be identified and some treatment regimes using interferon alpha have been licensed. The Advisory Committee on the Microbiological Safety of Blood and Tissue for Transplantation (MSBT) at its meeting 15 December agreed to advise Ministers of the four Health departments that:*

- i. In MSBT’s view there is a duty of care towards those infected with HCV as a result of NHS treatment. It follows that procedures should be put in place to identify those patients at risk;*
- ii. Whatever is done should be done equally and uniformly throughout the UK;*
- iii. Guidance should be drawn up as soon as possible:*
  - a) on procedures for identifying those at risk, and*
  - b) While it was for the medical practitioner responsible for each patient identified as at risk to decide what should be made known to the patient about his/her risk status, and to decide whether and what treatment should be advised, guidance on the counselling and treatment options would be desirable.”*<sup>1307</sup>

Subject to Ministers’ agreement, it was recommended that an ad hoc working party should be established to provide guidance on lookback.<sup>1308</sup>

The position in Scotland was flagged in this paper as a further complication. Dr Gillon’s study was highlighted and *“officials”* in Scotland were noted to have taken the stance that it was *“feasible and practicable”* to undertake a Hepatitis C lookback where they have *“a*

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1306 Submission from Roger Scofield to the Parliamentary Under-Secretary of State for Health 22 December 1994 p3 DHSC0032208\_149

1307 Submission from Roger Scofield to the Parliamentary Under-Secretary of State for Health 22 December 1994 pp3-4 DHSC0032208\_149

1308 Submission from Roger Scofield to the Parliamentary Under-Secretary of State for Health 22 December 1994 p4 DHSC0032208\_149

*clear legal duty to undertake such a programme.*<sup>1309</sup> Lord Fraser had instructed SNBTS to undertake a lookback.<sup>1310</sup> The paper noted that *“for one part of the UK to proceed to a look back on its own would be untenable.”* The need to *“maintain maximum commonality between policies throughout the UK”* was said to be important in order to minimise the risk posted by legal challenges.<sup>1311</sup>

In relation to cost, it was stated that the lookback exercise:

*“will have little direct cash cost for the Transfusion Service in identifying those at risk. The cost of follow up counselling and treatment would have to come out of present programme costs and no separate provision has been made for this. Assuming all 6000 people infected as a result of NHS treatment were to receive interferon treatment then the cost of the drugs could be as high as £12m. In practice, it is likely to be very much less than this. Some patients are already receiving treatment. Others would be unsuitable for it and as yet there is no evidence to show that its use on those who are asymptomatic is beneficial.”*<sup>1312</sup>

The paper concluded that *“the Department cannot dispute that a number of people have been infected through NHS treatment but deny negligence. The case does not have the same exceptional circumstances as did the HIV infection where those affected were all expected to die very shortly and were subjected to significant social problems including ostracism.”* In light of the decision not to establish a payment scheme, it was noted that *“there are practical steps that can be undertaken to assist those affected and those at risk.”*<sup>1313</sup>

Following this paper Tom Sackville agreed to the recommended Hepatitis C lookback exercise.<sup>1314</sup> Lord Fraser, while appreciating the *“sensitivities in proceeding in advance of the rest of the UK”*, had already decided to take the step of establishing a Hepatitis C lookback in Scotland.<sup>1315</sup> Following Westminster’s agreement to undertake a Hepatitis C lookback, the plan was for a harmonised approach.<sup>1316</sup> Westminster’s position was that the announcement could not go ahead until there was agreement between *“all Territorial Departments”*.<sup>1317</sup> This agreement between all three territorial health departments was reached by 10 January 1985.<sup>1318</sup>

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1309 Submission from Roger Scofield to the Parliamentary Under-Secretary of State for Health 22 December 1994 p4 DHSC0032208\_149

1310 Letter from Lord Fraser to Tom Sackville 22 December 1994 PRSE0001781

1311 Submission from Roger Scofield to the Parliamentary Under-Secretary of State for Health 22 December 1994 p4 DHSC0032208\_149

1312 Submission from Roger Scofield to the Parliamentary Under-Secretary of State for Health 22 December 1994 pp5-6 DHSC0032208\_149

1313 Submission from Roger Scofield to the Parliamentary Under-Secretary of State for Health 22 December 1994 p6 DHSC0032208\_149

1314 Memo from Andy Hollebton to Jonathan Mogford 4 January 1995 WITN5289020

1315 Letter from Lord Fraser to Tom Sackville 22 December 1994 p2 PRSE0001781

1316 Memo from George Tucker to the Minister’s private secretary January 1995 p1 DHSC0002551\_119

1317 Letter from Andy Hollebton to Roger Scofield 9 January 1995 DHSC0003555\_128, Hansard parliamentary question on Hepatitis C tracing January 1995 NHBT0005796

1318 Memo from Roger Scofield to Andy Hollebton 10 January 1995 p1 WITN5289021

## The establishment of a national Hepatitis C lookback

On 11 January 1995 the UK-wide Hepatitis C lookback programme was announced in Westminster in response to a parliamentary question.<sup>1319</sup>

A press release from Tom Sackville followed. It said that “*procedures have been established which make it possible to trace those at risk*”. The press release recognised that people who had received a blood transfusion before 1991 “*may be worried*” and if so they were encouraged to call the helpline. It recorded that the Minister had asked Dr Metters, Chair of the MSBT and the Deputy CMO, to bring together an ad hoc working party of experts to draw up guidance on the procedure for undertaking lookback and for counselling those identified as being at risk, as well as guidance on the treatment options available.<sup>1320</sup>

The announcement was accompanied by a letter from the CMO’s Office, produced by Dr Metters, providing additional information for GPs and doctors as well as a suggested script for the telephone helpline. The Q&A script included the following:

“Q: *What should I do if I have had a blood transfusion?*

A1. *A Look-back exercise is being established to identify those at risk. This is a process of identifying patients who were previously given blood from donors who have since been shown to be Hepatitis C positive ...*

A2. *The chances of your being infected are very small. You therefore need do nothing at present. You will be contacted in due course if you are discovered to be at risk. The look-back exercise may take some time to complete but there is no need for you to worry.*<sup>1321</sup>

The impression that these Q&A would have given to callers was that if they were not contacted by the lookback process then they had not been infected. Such an impression was wrong: only those donors who returned to give blood after 1991 would be identified as infected, thus allowing for recipient tracing. Donors who did not return to give blood were not identified but may still have infected recipients.

The announcement provoked many enquiries from concerned recipients of blood and blood products. By 18 January 1995, the helpline had handled 10,000 of these.<sup>1322</sup> Dr Elizabeth Love, deputy director of the Manchester RTC, wrote that they had been “*inundated*” with calls and “*astute callers*” had recognised that there were a number of donors who had donated before September 1991 but not afterwards whose Hepatitis C status was unknown. Dr Love noted

1319 Hansard parliamentary question on Hepatitis C tracing January 1995 NHBT0005796

1320 Department of Health Press Release *Hepatitis C and Blood Transfusions* 11 January 1995 NHBT0005792. A CMO letter was issued the same day. Letter from Dr Robert Kendell to all general practitioners 11 January 1995 PRSE0000412. There were also press releases in Scotland and Wales. SNBTS Press Release *Hepatitis C and blood transfusion in Scotland* 11 January 1995 PRSE0000495, Memo from Gail Williams to colleagues 12 January 1995 WBSV0002882

1321 Memo from the CMO’s office and Department of Health to all directors of public health 11 January 1995 p5, p7 HHFT0000002\_002

1322 Letter from Dr Robinson to Dr Frank Boulton 19 January 1995 p2 NHBT0088444

that such callers “*were not reassured by our standard answer.*” She stated that there was a requirement for “*clear, written guidance*” in relation to being able to offer screening tests at transfusion centres (as opposed to GPs undertaking testing) and queried who was to fund such tests.<sup>1323</sup>

On 20 January 1995 the lookback working party which had been announced by Tom Sackville first met to discuss the Hepatitis C lookback. The aim was for the lookback exercise to be completed by the end of summer. The first priority was to agree guidance for the blood transfusion services in the four UK health departments on the identification of units of blood which might be infected. It was agreed that the lookback exercise would concentrate at first on donors who had given blood prior to September 1991 and had been found to be Hepatitis C positive on a subsequent visit. It was agreed that blood services would not try to trace donors who had not come back to a transfusion centre since then because “*the work involved in doing so would be disproportionate to the benefit.*” There was consideration of testing serum samples stored before September 1991 but this was also deemed to be disproportionate, though a legal view on this was said to be necessary. Standard letters to blood banks and to GPs concerning recall of patients for counselling and testing were suggested by Dr Gillon. He was requested to produce draft guidance on counselling based on existing material used by SNBTS.<sup>1324</sup>

By 14 March 1995 Scotland was noted to be ready to proceed but was waiting for the other nations “*to catch up.*”<sup>1325</sup> Professor Keel acknowledged that Scotland could have proceeded with a lookback exercise before the rest of the UK and said:

*“But you have to remember that patients cross the border between Scotland and England, and vice versa, so that there was that. It was just seen as desirable that in such an important area, that the whole of the UK did it roughly at the same time ... Well, I think clinicians would have said -- well, if we’d gone ahead in Scotland with our own exercise, I think clinicians south of the border would have said, ‘Why are we not doing it here?’ ... I definitely think if we’d gone it alone, so to speak, English clinicians would have been a bit bemused as to why they weren’t being asked to do it at the same time.”*<sup>1326</sup>

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1323 Letter from Dr Love to Dr Robinson 17 January 1995 NHBT0002754

1324 Notes of Hepatitis C Look Back Working Party meeting 20 January 1995 pp1-2 NHBT0009715. Counselling in the traditional medical sense of imparting information, rather than in the modern sense of counselling. Written Statement of Dr Angela Robinson para 450 WITN6926003

1325 Notes of Hepatitis C Look Back Working Party meeting 14 March 1995 p1 WITN4461155. Dr Metters had written to the Scottish CMO the previous month to say that the establishment of the working party gave “*no reason for Scotland to go it alone*”. Letter from Dr Metters to Dr Kendell 14 February 1995 DHSC0003555\_236

1326 Professor Aileen Keel Transcript 26 July 2022 pp133-134 INQY1000234\_002



After a number of meetings and much correspondence working out the practicalities of the programme,<sup>1327</sup> the CMO sent out a “Dear Doctor” letter on 3 April 1995 which provided the guidance and procedures for the UK-wide lookback already announced.<sup>1328</sup>

The letter refers to the purpose being “*to trace, counsel and if necessary treat those people who may have been inadvertently infected with hepatitis C through blood transfusions.*” Guidance was set out in Annexes. Annex A containing the procedural guidance refers to the regional transfusion centre’s action as “*All reference laboratory confirmed HCV antibody donors to be identified and their donor record examined.*” The process for informing recipients was that the RTC would write to their original treating consultant asking whether they wanted to “counsel” the patient themselves. If they declined then contact would be made with a current consultant or GP asking whether it was appropriate to contact the patient and whether the consultant or GP preferred to make that contact. The RTC were to contact them directly if the GP did not wish to. The flowchart specifically shows that if the patient had been tested and was positive, then they should be referred to a hepatologist or gastroenterologist.<sup>1329</sup> There was no indication in this Annexe that the procedures were limited to donors who donated again after 1991. However, in Annexe B (which set out guidance for counselling patients) this was made clear.<sup>1330</sup>

For some working in the BTS, this was a rather sudden announcement.<sup>1331</sup> For example, Dr Lorna Williamson, of East Anglia BTS, recalls receiving information about lookback on a Friday with the lookback starting on the Monday.<sup>1332</sup>

In late 1995 and early 1996 there was concern that the lookback was making slow progress. In October 1995 Dr Andrzej Rejman reported to Dr Metters that it was clear that the lookback exercise was “*not being pursued with enough vigour*”.<sup>1333</sup> The MSBT examined progress at its meeting on 8 January 1996.<sup>1334</sup> Dr Metters mentioned increasing press enquiries about why the exercise was going slowly and why ministers were not taking action. Two key bottlenecks were identified: hospital records and counselling. If both these areas of difficulty were overcome, it was likely that hepatology services for specialist assessment

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1327 For the precise chronology see Written Statement of Dr Angela Robinson paras 451-500 WITN6926003

1328 Letter from Dr Calman to doctors 3 April 1995 NHBT0002796\_002. See also Letter from Dr Kendall to doctors 3 April 1995 PRSE0003526

1329 Letter from Dr Calman to doctors 3 April 1995 pp3-6 NHBT0002796\_002

1330 It read: “Transfusion services in the UK began screening for antibodies to HCV on 1 September 1991. Patients transfused subsequent to that date have a negligible risk of having been infected by transfusion. Not all of those transfused with potentially infectious blood prior to the commencement of testing will, however, be identified by the ‘look back’ procedure; as this relates to donors who have given blood since HCV testing was introduced in September 1991. For patients transfused prior to September 1991, it may only be possible to provide full reassurance by offering to test them for antibodies to HCV.” Letter from Dr Calman to doctors 3 April 1995 p7 NHBT0002796\_002

1331 See for example: “*If anyone has gleaned any more than I have, please do share it!*” Memo from Dr Sue Knowles to Dr Lorna Williamson and others 24 March 1995 NHBT0012321\_001

1332 Dr Lorna Williamson Transcript 8 December 2021 pp92-93 INQY1000169

1333 Memo from Dr Rejman to Dr Metters 9 October 1995 DHSC0003538\_016

1334 Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting 8 January 1996 DHSC0020692\_118

and treatment would not be able to cope. Dr Metters provided a submission to ministers on 5 February 1996 which outlined the position.<sup>1335</sup> The MSBT's overall view was reported as being that "*central exhortation to speed up the Look-Back process would be unlikely to achieve much.*" Dr Metters agreed and ministers were asked not to take any particular action. Lord John Horam has told the Inquiry that upon receipt of Dr Metters' submission, he agreed to continue with the current course of the Hepatitis C lookback, accepting Dr Metters' suggestions of improving communication between the Blood Transfusion Service and hospitals where there were particular problems and "*offering assistance to overcome the bottlenecks.*"<sup>1336</sup>

From 1 April 1996 the Hepatitis C lookback was expanded to include Hepatitis C indeterminate test results.<sup>1337</sup>

During the late 1990s the lookback slowly wound down as fewer cases were identified.

The outcome of the Hepatitis C lookback in England was formally reported. 50% of tested recipients were found to be infected with Hepatitis C. 4,432 recipients of 6,687 blood components were identified. 1,067 blood recipients were reported as having been traced for testing. The fate of 31% (2,101) of components was not identified due to inability to access information from records. 61% (2,717) of identified recipients were known to be dead at the time of tracing.<sup>1338</sup> Of the 669 transfusion-transmitted infections identified, 92% were first diagnosed by the lookback programme.<sup>1339</sup>

### The approach to Hepatitis C lookback in Wales and Northern Ireland

Although the National Blood Transfusion Service (Wales) took part in the national lookback in 1995, there is no material to show that the Welsh Office were directly involved in the decisions to consider it (or not to do so, for the time being) nor in the eventual decision to recommend it. Though plainly aware that a lookback was to be announced on 11 January 1995,<sup>1340</sup> a briefing note prepared a few days later appears to reflect much of what had

1335 Memo from Dr Metters to Marguerite Weatherseed 5 February 1996 DHSC0004469\_013, Hepatitis C Look Back: Proposed Alternatives Ways Forward DHSC0004469\_027

1336 Memo from Marguerite Weatherseed to Dr Metters 4 March 1996 DHSC0002533\_152. Written Statement of Lord John Horam paras 2.120-2.126 WITN5294001. An annex to a submission in December 1996 recorded "*Ministers decided not to speed up detection as the bottleneck would then transfer to hepatology clinics.*" Memo from C Philips to Mr Fahy 23 December 1996 p7 DHSC0004203\_013

1337 Draft letter from Dr Robinson 1 March 1996 NHBT0036529, Written Statement of Dr Angela Robinson paras 582-585 WITN6926003

1338 Probability of receiving testing in a national lookback program: the English HCV experience p1, p2 NHBT0097156\_005. For other published reports of the English Hepatitis C lookback see Soldan et al *The contribution of transfusion to HCV infection in England* Epidemiology and Infection vol 129 2002 PRSE0000620 and The English National Blood Service HCV Lookback Collation Collaborators *Transfusion transmission of HCV infection before anti-HCV testing of blood donations in England: results of the national HCV lookback program* Transfusion September 2002 NHBT0097156\_004

1339 Written Statement of Dr Angela Robinson para 626 WITN6926003

1340 A note for a meeting of the Welsh Health Common Services Agency (WHCSA) on 26 January shows that action had already been taken to prepare for a lookback before 11 January: a guidance sheet had been prepared for hospitals and an information sheet for staff. Note from F Williams of NBTS (Wales) on HCV lookback 26 January 1995 WBSV0002875

been set out in the Department of Health submission of 22 December. It recorded that “*The reason for the decision to instigate lookback now seems to have been based on*” four matters – the recommendation of the MSBT; the *Panorama* programme which had been due on 9 January but was broadcast on 16 January, raising the issue; “*improved record keeping allowing the tracing of all donations relatively easily from source to patient*”;<sup>1341</sup> and the licensing of interferon alpha as a “*palliative treatment*” for Hepatitis C. This wording and the way in which the Department of Health submission was reflected in the briefing note suggest that there was no truly independent consideration brought to bear by those in Wales. The events described occurred prior to devolution, and NBTS(Wales) followed the lead of the Department of Health. Its involvement in the lookback was also prior to devolution and the Welsh blood services “*fed their findings directly back to the Department of Health*” in London.<sup>1342</sup>

As at January 1996 the position with regard to tracing hospital records was described as “*dismal*”.<sup>1343</sup> In May 1998 figures from the Welsh Blood Service were presented. 115 pre-1991 donors had been identified. 653 recipients had been identified and followed up. 457 recipients had died. 166 recipients were counselled and tested. 74 were positive, 88 were negative and four results were still outstanding.<sup>1344</sup>

As with Wales, in 1995 healthcare in Northern Ireland was not a devolved issue and Northern Ireland followed the approach of the Department of Health in London.<sup>1345</sup> The lookback in Northern Ireland was undertaken by the Northern Ireland Blood Transfusion Service (“NIBTS”). On 3 April 1995 a letter went to all hospital consultants and GPs in Northern Ireland. The “*hope [was] that [the lookback] exercise would be completed*” in 1995.<sup>1346</sup>

On 23 May 1995 a report was produced about the Hepatitis C lookback in Northern Ireland. 23 Hepatitis C positive donors had been identified and 8 of these were new donors. It was noted that the transition from manual to computer records for a period in the 1980s was “*causing difficulty tracing donations.*” Issues about legal liability, the need for additional resources, difficulties in tracing hospital records and doubts about clinical colleagues wishing to undertake counselling and testing were all flagged as concerns.<sup>1347</sup>

On 19 July 1996 the Deputy CMO, Dr Ruth Hall, wrote providing an update on the lookback exercise. The NIBTS had identified 20 Hepatitis C positive donors since screening was

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1341 By way of comment, this is what had been recommended in 1952 by the Expert Committee on Hepatitis of the World Health Organization. It should have been done. It also makes no sense as a reason for delay until “*now*”, since it is difficult to understand why after five years records should now be in a state to permit what – on this understanding – they did not permit then nor before then.

1342 Written Statement of Vaughan Gething para 30 WITN5665001

1343 Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting 8 January 1996 p2 DHSC0020692\_118. Despite what had been said in the briefing note.

1344 Fax message from Dr David Hutton to Dr Robinson 28 May 1998 p1 NHBT0002790\_002

1345 Written Statement of Robin Swann para 8.5 WITN5570001

1346 Letter from Dr Hall to chief executives of acute trusts and and consultant haematologists 19 July 1996 BHCT0004009\_001

1347 Hepatitis C Lookback Northern Ireland Report 23 May 1995 NHBT0040501\_004

introduced in September 1991.<sup>1348</sup> As at July 1996 records of 120 components donated by those 20 donors were traced. 43 components had not been traced. It was noted that *“Tracing the components and recipient has proved to be a complex process”*. It was hoped that *“the complete tracing and identification exercise will be completed by the end of 1996 across the United Kingdom.”*<sup>1349</sup>

In April 2001 two donors came *“after a long interval”* and were found to be Hepatitis C antibody positive. The two donors had donated in the 1980s. Dr Frank Jones, consultant haematologist of the Royal Group Hospitals in Belfast, was asked by Dr Kieran Morris, consultant in transfusion medicine of NIBTS, to assist in tracing any recipients. Red cells were issued at the Royal Victoria Hospital on 20 November 1989 and on 20 May 1995.<sup>1350</sup> Dr Jones states that the *“blood bank was able to trace all of these blood products to their recipients. I then requested the patient’s charts from medical records and went through them to confirm that the patient had received the identified product. It was not uncommon to find that the patient was deceased, as someone who has sustained major trauma will inevitably have a considerable number of units of blood and blood products.”* If the patient was alive, then Dr Jones identified the relevant clinician or GP and informed the NIBTS of these. Follow-up would then be arranged by the relevant clinician or GP.<sup>1351</sup>

### The course of the lookback in Scotland

A progress report for Scotland as at 25 May 1995 reported a range of experiences. The west of Scotland haematologists were expressing concern at the amount of time and effort the lookback process would demand of them; and in the north-east region reluctance was encountered on the part of consultant haematologists and GPs with respect to *“seeing”* patients. The north and south-east regions had completed tracing and were contacting patients; in the east donations had been traced but patients not yet contacted. In summary: *“Implementation process has been problematic ... However, good progress is being made.”*<sup>1352</sup>

In April 1998 Professor Ian Franklin wrote to Dr Keel following a review of the status of the lookback by the SNBTS Medical and Scientific Committee. Progress had been virtually static over preceding months. There were still a number of patients whom they had been unable to trace: without additional resources, doing so was not going to be possible. The view was that the lookback should be considered to be closed *“unless, of course, SOHD*<sup>1353</sup> *feel that it should resource one final effort to conclude every possible case.”*<sup>1354</sup>

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1348 This is a lower figure to the 23 people in the 1995 report.

1349 Letter from Dr Hall to chief executives of acute trusts and consultant haematologists 19 July 1996 BHCT0004009\_001

1350 Letter from Dr Morris to Dr Jones 5 April 2001 NIBS0001311\_002

1351 Written Statement of Dr Frank Jones para 95.1 WITN5559001

1352 HCV Lookback Scottish Progress Report 25 May 1995 NHBT0088395. See also Minutes of SNBTS Medical and Scientific Committee meeting 17 May 1995 SBTS0000463\_005

1353 Scottish Office Department of Health.

1354 Letter from Professor Franklin to Dr Keel 28 April 1998 PRSE0003277. The Scottish Office agreed that the steps that had been taken already were sufficient. Letter from John Aldridge to Dr Keel 12 May 1998 PRSE0000262

Following a meeting of the MSBT on 4 June 1998, it was agreed that all reasonable measures had been taken to trace components and recipients in Scotland, and that the tracing exercise could stop. Reasons for non-traceability of components or recipients, however, had to be logged onto the lookback register before the exercise could be considered formally closed.<sup>1355</sup>

## Why wasn't a national Hepatitis C lookback started earlier?

It is obvious that as soon as there is a test which can identify donors who suffer from an infection transmitted by blood it ought to be possible to see if their donations have transmitted that infection to others. In the same way, as soon as it is possible to identify that a person who has received a transfusion has become infected, and that this is probably because of the transfusion rather than because of some other cause, then it ought to be possible to identify those who have given blood to that person. They may then be checked to see if they are themselves suffering and may be at risk of passing the infection on to someone else. In each case, reliable and up-to-date records will be needed, and action needs to be swift if most donors, or recipients, are to be traced.

In the case of either donor or recipient "counselling" will be needed, so that they are clear as to what might be the case, and given the best information about what has happened and its possible repercussions, as well as how likely it may be that they will suffer such consequences.

Given that these propositions are obvious, they lead inexorably to a conclusion that as soon as a test is used universally to screen donations it can and should be used forthwith to identify people who were, or have been, infected so that they can receive appropriate care and know of their position.

The account of delays, avoidance of the issue, indecision and passing of the buck set out above demand explanation. Why was it that Hepatitis C lookback did not begin more or less contemporaneously with the introduction of universal screening?

The account shows that there were a number of reasons.

First, between 1988 and 1989 there was no test. From 1989 to 1 September 1991 there was: but not one which was universally adopted in the UK. There were pilot studies: and the account shows that from the earliest of these (1989) clinicians involved thought a lookback exercise would be valuable – but a reason for caution was the risk that if told they might have received infected blood a patient could sue for product liability.<sup>1356</sup>

The second reason was there were thought to be problems with counselling donors given that it was as yet unclear what the significance of a positive test might be.

A third (in mid 1990) was that tests and policies were at an evolutionary stage: it was seen as a matter for later decision.

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1355 Letter from Dr Keel to Professor Franklin 10 June 1998 PRSE0004337

1356 See the section on *Consideration in 1989* above.



A fourth was that funding was lacking. Testing, confirmatory testing, and counselling would all have to be paid for; and to run a lookback involved effort in addition to all the other demands it would make on health service personnel.

A fifth was that part of the justification used by the Department of Health for there being no national lookback *“was that there was no treatment available for hepatitis C, so one would be seeking out individuals, establishing whether or not they had been infected with hepatitis C but then having nothing in the form of treatment to offer them.”*<sup>1357</sup>

A sixth was that a lookback necessarily involved telling an individual they may have been infected, not least because a further test was needed to confirm whether they probably were or not: and this might cause unnecessary worry and possibly distress.

A seventh was that if a donor or recipient tested positive, to present someone with the results of a test and then tell them that nothing can be done for them (there was no treatment which could be offered)<sup>1358</sup> was harsh, and for some health professionals felt like doing their patients a disservice. This later morphed into the question whether treatments were effective, becoming no longer a question of “we have no treatment” but now “we have a treatment, which will be demanding, but where there is a substantial risk of failure.”

All these reasons appear from time to time in the account of the years from 1988 to 1995. To them should be added what Dr Robinson had to say: that the available tests were not wholly reliable. A positive test might be a false positive, and in some cases would be.<sup>1359</sup>

## What was the impact of the delay?

The delay in establishing a national Hepatitis C lookback was felt both on individual and wider levels.

Gill Fyffe was unwell for seven years after her transfusion before she was identified as having been infected with Hepatitis C in the lookback in 1995. During that time, she had been caring for her two young children and she says *“I am very grateful that the look back*

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1357 This was Dr Hewitt’s understanding of the Department of Health’s position. Dr Patricia Hewitt Transcript 10 December 2021 p5 INQY1000171. Dr Rejman told the Inquiry he thought *“the principle that identification of a disease or infection was not – generally – warranted if there was no useful treatment that could be offered, would have been widespread”* and noted a minute copied to him from Dr Metters about Hepatitis C screening: *“There would be little point introducing a screening programme if there is no effective treatment.”* Written Statement of Dr Andrzej Rejman para 122.3 WITN4486040, Letter from Dr Metters to Dr Nicholas 17 March 1994 DHSC0002546\_019

1358 Of course, lifestyle advice could be given as to diet and drink; what might make the condition worse; and what precautions were advisable to protect people close to the infected person. It would also put someone in a better position to understand what might be happening to them, to monitor the position, and to take advantage of any new treatments as and when they first arose.

1359 *“Before we made the decision to tell donors or recipients, we had to know what we were telling them, that it was reliable information — and who we were telling. Hepatitis C might be serious in some people, but the serious consequences might not manifest for 30 years and even when we commenced the lookback in 1995, what treatment there was available was only recently licensed and still experimental. We could put a blight on the lives of many people, without hope at that stage for an undetermined possible good for some of them. There was a belief that we ran the risk of doing quite extensive harm, for an undefined benefit to a small number of people.”* Written Statement of Dr Angela Robinson paras 410-413 WITN6926003

*survey found me. I wonder whether it might have been commissioned earlier ... I think that that is the bigger question, why were my children at risk for seven years?*<sup>1360</sup>

Elaine Turner was infected with Hepatitis C when she was given a blood transfusion after the birth of her second child in 1989. She had her third child in 1996 and was called into her GP surgery shortly after the birth for a blood test. The GP told her it was part of the lookback programme. She was informed of her infection by phone when she was home alone with her new baby and says: *“When I was given the diagnosis I was shocked. I realised I had been living with the infection without knowing it for seven years and may have passed it on to my husband or children. My first thought was whether I had passed it on to my tiny baby.”*<sup>1361</sup>

Another woman was infected with Hepatitis C from a blood transfusion when she was young and was also diagnosed in 1997 through the lookback programme. She says the nurse *“did talk to me about the risks of passing on the infection through blood to blood contact and sexual intercourse. She told me the risks were small. I had two young boys at this point and all I could think about was if they also had hepatitis C.”*<sup>1362</sup>

Other people were denied the opportunity to make choices about their lifestyle to mitigate the risks arising from the virus because their infection was not identified during the lookback. Margaret Sharpe was most likely infected with Hepatitis C when she was given transfusions after a road traffic accident in 1974, or after further surgery related to the accident in 1977. Margaret was diagnosed with Hepatitis C in 2013. She said *“I feel totally confused and let down that I was not contacted in 1991 ... and feel bound to ask how different my life may have been had I been tested then”*.<sup>1363</sup>

For others, the delay meant that the lookback programme could not contact them. One man was diagnosed with Hepatitis C in 2011 after a transfusion in 1991. He discovered when he obtained his medical records that:

*“the LookBack programme had attempted to get in touch with me in 1995 and 1996. It appears from my records that they wrote to me on three occasions once via my GP dated 17 August 1995, once directly to me dated 3 October 1995 and again directly to me dated 15 January 1996. The two letters to me were to two different addresses. None of these letters reached me including the one that was written to my GP ... I was a student at the time and was moving around a lot and moved to Manchester on 6 January 1996. As I was on asthma medication I would have registered promptly with the GP in Manchester. I have no idea why previous or subsequent GPs did not communicate this information to me. I understand that the GP received another letter dated 12 February 1996 which stated that two attempts were made to contact me and to refer me for counselling and since they had heard nothing they would close my file. I believe that this happened.*

1360 The Fyffe Family Transcript 3 July 2019 pp128-129 INQY1000026

1361 Written Statement of Elaine Turner para 19 WITN2702001

1362 Written Statement of ANON para 10 WITN2156001

1363 Written Statement of Margaret Sharpe p13, p23 WITN2546001

*No further attempts were made to trace me ... The whole time this information was on my file, it was obvious what the problem was, I was attending my GP because I was sick and this information did not reach me. The information on the file would have answered all my questions and would have stopped me taking antidepressants for 10 years.”*<sup>1364</sup>

On a wider level, the lookback was less successful than it would have been for a number of reasons related to the delay.

First, as the lookback began in April 1995 and was concerned with blood given before September 1991, donors who had not presented since September 1991 had by this time been “*out of contact for at least 4.5 years. The chance of being able to trace any individual diminishes as time passes.*”<sup>1365</sup> This delay meant that “*vital time*” was lost from “*first knowing of a donor whose previous donations would require investigation.*” Dr Hewitt has told the Inquiry that “*the majority of HCV infected donors were identified in the first 12 months of screening*”.<sup>1366</sup> Therefore, donations that could have been traced and recipients found were lost to follow-up.

Professor John Brennan, interim medical director of Liverpool University Hospitals NHS Foundation Trust, describes that the “*major obstacle*” faced by his Trust was reaching patients who were “*lost to follow up*”. In particular, this concerned patients who had moved house or were “*choosing to not respond to letters sent.*”<sup>1367</sup>

With less delay, it is likely that fewer people would have been lost to follow-up. The connection with their original treating consultant and/or GP is likely to have been stronger and tracing individuals would likely have been more straightforward.

Second, lookback relied on testing of the blood of those who were repeat donors and had returned to the blood services to donate. Donors who had stopped giving blood were not sought out and tested. Drs Robinson and Hewitt described that it was not appropriate to search out those who may have stopped donating due to “*relocation, illness, death or a material change in their circumstances*”<sup>1368</sup> and that doing so would be unlikely to identify many positive donors whose donations could then be followed up.<sup>1369</sup> Dr Hewitt estimates this would have involved contacting at least 200,000 people each year prior to 1991.<sup>1370</sup> This was a view shared by SHHD on the basis that it would be “*logistically extremely difficult*” and “*any benefit would be disproportionate to the benefit required*”.<sup>1371</sup> However, by only testing

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1364 Written statement of ANON para 7c WITN2001001

1365 Written Statement of Dr Patricia Hewitt para 331 WITN3101006

1366 Written Statement of Dr Patricia Hewitt para 294 WITN3101006

1367 Written Statement of Professor John Brennan para 89 WITN7095002

1368 Written Statement of Dr Angela Robinson para 646 WITN6926003

1369 Written Statement of Dr Patricia Hewitt para 326 WITN3101006

1370 Written Statement of Dr Patricia Hewitt para 332 WITN3101006

1371 Written Statement of Professor Aileen Keel para A39 WITN5736003

the donations of returning donors, a proportion of donors, who may have been infected, were not tested.<sup>1372</sup>

Dr Robinson reflected that attempting to trace anyone who had had a blood transfusion and testing them would have resulted in *“a tiny percentage of people being identified and the scale of the exercise would have been huge.”*<sup>1373</sup>

While there were good reasons not to test donations that had been given prior to 1991, the decision not to offer testing for all recipients of blood before 1991 was wrong. Importantly, the information that was produced in relation to the lookback exercise appeared to suggest that anyone who was infected would be identified when this was simply not the case. This message was communicated to both the public and professionals, including GPs. They were therefore operating under the misapprehension that patients who had contracted Hepatitis C would have been told about it through the lookback.

For example, one woman explains that she received a blood transfusion in 1980 and then *“In around 1995, I heard about the Look Back scheme and I thought I would be called and told there was something in my blood. I thought they would get in touch with me if there were any concerns about my health. When they did not it gave me hope (which turned out to be false) that I was ok and it was all in my head. Over time I dealt with it and processed it in my mind and began to believe I was ok.”* She was diagnosed with Hepatitis C in 2012 having suffered for many years with fatigue and depression.<sup>1374</sup>

Margaret Donnelly had received a blood transfusion in October 1990 and saw a program about the lookback in 1995. There was a helpline number provided and she phoned it:

*“I received a booklet with some information and contacts. I then decided to see my GP ... [who] looked up information on his computer and said he thought that since the government had said the ‘look back’ would check blood donated during the time I had the transfusion he would be notified if there was a problem. He did say that I could contact the Southern General Hospital and tell them when I had the transfusion but I didn’t do this as I thought if everyone who had received blood did that the hospital would be overwhelmed. After about two years on a routine visit ... I asked him about the ‘look back’ and he said that since he had not heard anything I must be in the clear. Neither he nor I realised that the ‘look back’ had such a restricted remit.”*<sup>1375</sup>

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1372 At the Health Committee meeting on 18 April 2006 Shona Robinson, MSP for the Scottish National Party and Member of the Scottish Parliament’s Health Committee, stated that *“The term ‘look back’ implies that all cases were looked at, but they were not. The exercise concentrated only on those donors who happened to come back to give blood. It did not address hep C infection from donors who did not come back.”* She described it as *“a totally inadequate exercise in attempting to trace people who could have been infected.”* Scottish Parliament Health Committee Official Report 18 April 2006 p14 CBCA0000007

1373 Written Statement of Dr Angela Robinson para 652 WITN6926003

1374 Written Statement of ANON paras 8-9 WITN1871001

1375 Written Statement of Margaret Donnelly paras 4-5 WITN2126001

She was diagnosed with Hepatitis C in 2005.

Third, there were significant difficulties completing lookback investigations due to missing medical records. A SACTTI meeting on 16 April 1996 found that a *“major limiting factor to completion of the look-back”* was the unavailability of medical records.<sup>1376</sup> Dr Hewitt describes that the 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.”* She states that *“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.”*<sup>1377</sup> By way of comment, it is a pity that laboratories disposed of records when it was very much on the cards that a lookback was imminent, and it should have been realised that a lookback would need those records if it was to be effective: this, it seems, is a consequence of not instituting lookback as and when universal screening began.

Some hospitals and clinicians did not engage enthusiastically in the lookback. Dr Robinson told the Inquiry that *“We tried to get a letter from the CMO to enforce compliance from those hospitals who were not complying with our request for records.”*<sup>1378</sup> In her view there was no deliberate attempt not to comply with lookback, but some hospitals *“faced more obstacles and handicaps than others due to the lack of personnel or where records were missing”*.<sup>1379</sup> The effect of this on individuals was a lack of information or a delay in informing them of their infection. Fiona Cunningham received a blood transfusion during childbirth in 1989. She became unwell in 2015 and was diagnosed with Hepatitis C. She explains: *“I lived with HCV without knowing for 26 years. I was never contacted by the NHS or a hospital during the period of time between the transfusion and my diagnosis. I am concerned that a look-back exercise was not conducted.”* She was diagnosed with liver cancer and underwent a liver transplant in 2017.<sup>1380</sup> John Aubrey was contacted by letter in 1995, five years after he had surgery for ulcerative colitis during which he received blood transfusions. The letter asked him to contact the head of the haematology centre where he had originally been treated. When he saw the clinician, he was told that *“they had been looking for me for 5 years, and the doctor apologised for the length of time it had taken to locate me but none of the medical establishments had my address. I find this astonishing, and nonsense, because my medical records were with the local GP, plus I was still under Neath General Hospital in relation to my Colitis issues. I was having six monthly check ups.”*<sup>1381</sup>

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1376 Minutes of SACTTI meeting 16 April 1996 p2 NHBT0000088\_013

1377 Written Statement of Dr Patricia Hewitt para 294 WITN3101006

1378 Written Statement of Dr Angela Robinson para 674 WITN6926001

1379 Written Statement of Dr Angela Robinson para 693 WITN6926001

1380 Written Statement of Fiona Cunningham para 41 WITN0062001

1381 Written Statement of John Aubrey para 11 WITN0071001



Where patients had died prior to the lookback exercise, the passage of time meant some hospitals struggled to establish a cause of death for patients during lookback exercises. This was information that was requested by lookback forms. For example, Dr Williamson, of the East Anglian Blood Transfusion Centre, found that while hospital computers could tell them that a patient had died, it was much more difficult to obtain the cause of death as this involved retrieving medical notes which was a much more “*labour intensive, time consuming and costly*” exercise.<sup>1382</sup>

### Other criticisms of the lookback process

Those who were contacted through the lookback process are critical of how they were informed of their infection, the information they received and the delays in being able to see a clinician who could adequately explain the position to them. David Lane recalls that his father had received a blood transfusion in 1989 as he had lost a lot of blood through rectal bleeding. He describes his father receiving a letter “*totally out of the blue in 1995. It wasn’t recorded delivery or anything; it was like an invite to a sale. It said ‘in 1989 the donor was infected with Hepatitis C – please see your doctor’. We were all absolutely gobsmacked ... When dad went to the GP, the doctor didn’t really know much about the issue.*”<sup>1383</sup> One man received a letter from the Blood Transfusion Service directly to him despite only being aged 9: “*The only reason I knew it was a letter for me was because I thought it was a love letter as it had a logo with two hearts and a crown on it*”. He cannot recall what the letter said and gave it to his mother. He was subsequently diagnosed with Hepatitis C.<sup>1384</sup> Another woman describes how the letter included a section at the bottom that was highlighted “*emphasising that there was no relationship between hepatitis C and HIV/AIDS. The first thing you look at is what’s highlighted. It started to make me wonder what I’d got.*”<sup>1385</sup>

One man was informed by his GP that he had received infected blood and he was invited to be tested. After the first test, his GP wrote to him again indicating that he needed further tests. Having waited two weeks, the man had not heard from his GP so booked an appointment to see him and he was told that he had tested positive for Hepatitis C.<sup>1386</sup> Similarly, a woman, who had contracted Hepatitis C through a blood transfusion around childbirth, was telephoned by the practice nurse at her GP surgery and asked to attend to discuss something. Her GP had received a letter from the NBTS informing him that she “*had been identified as a suspected recipient of contaminated blood.*” Her GP was “*outraged and shocked, and was uneasy that the Service had attempted to make contact with me through him. He told me that he would make them write to me directly.*” She subsequently received a letter from the NBTS.<sup>1387</sup>

1382 Letter from Dr Williamson to Dr Robinson 9 May 1995 NHBT0005879\_017

1383 Written Statement of David Lane paras 6-7 WITN0038001

1384 Written Statement of ANON para 3 WITN0279001

1385 Written Statement of ANON para 3 WITN0074001

1386 Written Statement of ANON paras 3-4 WITN0562001

1387 Written Statement of ANON paras 10-11 WITN0580001

Anthony Hughes received a letter from the blood services in the summer of 1995 explaining that they were doing a lookback programme for the period of 1986-90 and they wanted him to contact them: *“They didn’t explain why but my professional knowledge gave me a strong clue as to what it was about.”* He had received a transfusion in 1988 for a bleed in the colon arising from an E. coli infection. Anthony went to the service and was tested: *“Despite the 3-week long delay in obtaining the result, I waited patiently and refused to fall to pieces.”* He was informed that he had contracted Hepatitis C and there was nothing that could be done: *“When I asked the consultant who came to deliver the bad news what the survival rate for hepatitis C was he told me that I ‘wouldn’t live to see the next century’ ... The whole process wasn’t done in a patient-centred manner at all and there wasn’t any treatment discussed or given to me by the consultant so I was simply told and left alone to deal with the aftermath.”* Some weeks later he was contacted by a haematologist, who had an interest in Hepatitis C, whom he knew through his work and was monitored by him.<sup>1388</sup>

One woman waited for two months between being told she had been infected with Hepatitis C from a transfusion after childbirth until it was explained to her what that meant. For those two months, she says *“I was not given any guidance on how to manage the condition. I was worried I had infected my family and I thought that I had definitely infected my boys. At that point in time, I thought you could transmit the disease through saliva, which heightened my worries.”*<sup>1389</sup> By contrast, Robert Worsley received a letter from the blood transfusion service and attended an appointment with his GP: *“The doctor at my GP Surgery had researched the whole thing properly and carefully and he explained that I had contracted Hepatitis C and it was highly infectious and could be passed on to others.”* Physically the Hepatitis C had not affected him at all by that stage and he says he would never have known about it had he not been contacted through the lookback programme.<sup>1390</sup>

Informing someone about their infection is evidently personal to the individual concerned. In the absence of a well-developed relationship (such as that between many GPs and their patients) it can be particularly difficult to know how best to do it: blood services, usually without any such relationship, would not find it easy. There were some patients who preferred to be told by a trusted clinician and others who preferred direct contact. Delay in access to a clinician who understood the condition and could give proper advice and guidance was more problematic.

However, the lookback process would have benefited from being established in every region with involvement from hepatologists who were ready and able to see patients identified in the lookback without delay, particularly given the often lengthy periods between infection and diagnosis.

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1388 Written Statement of Anthony Hughes paras 15, 21, 27, 28, 45 WITN0262001

1389 Written Statement of ANON para 21 WITN0277001

1390 Written Statement of Robert Worsley paras 5.2, 5.5 WITN0331001

## Lookback after the Penrose report

In March 2015 the Penrose Inquiry produced its final report. It made one recommendation: *“That the Scottish Government takes all reasonable steps to offer an HCV test to everyone in Scotland who had a blood transfusion before September 1991 and who has not been tested for HCV.”*<sup>1391</sup> The basis for this was that:

*“The legacy of the period when viral transmission via blood and blood products was occurring continues to be severe for many people, whether due to ill-health or loss of a loved one. There is one respect in which the Inquiry can recommend action to prevent suffering from being greater than necessary – the detection of those whose transfusion-transmitted Hepatitis C infection is still undiagnosed. These will be people who received a transfusion of blood or blood components from a donor who was HCV-positive in the period before the introduction of screening for the virus and who acquired HCV but have not yet been diagnosed.”*<sup>1392</sup>

On 25 March 2015, Jeremy Hunt as Secretary of State for Health laid a written ministerial statement as an interim response to the Penrose Inquiry. This did not mention the recommendation to implement Hepatitis C testing.<sup>1393</sup>

The following day, Andy Burnham asked *“about the one recommendation that the Penrose report makes: that all people in Scotland who had a blood transfusion before 1991 now be tested for hepatitis C. Does the Minister think that recommendation should apply in England?”*<sup>1394</sup> The Parliamentary Under-Secretary of State for Public Health, Jane Ellison, responded: *“I can confirm that the Department of Health concluded a UK-wide look-back exercise in 1995 to try to identify everyone who might have received infected blood prior to 1991, but the Department will consider if anything more can be done on this in England. That work is very important and will be undertaken.”*<sup>1395</sup>

An analysis and options for the implementation of the Penrose recommendation in England was undertaken during May, and four options put forward to Jane Ellison on 12 June 2015.<sup>1396</sup>

The background to these options was set out as including that: *“DH previously ran a HCV awareness campaign which had a total spend of c£13m. The campaign, most recently known as ‘Get Tested, Get Treated’ was launched in 2004/05 and ran until 2009/10. This campaign was initially run as a general national campaign before becoming targeted towards high risk*

1391 The Penrose Inquiry Final Report March 2015 p1778 PRSE0007002

1392 The Penrose Inquiry Final Report Executive Summary March 2015 pp48-49 PRSE0007001

1393 House of Commons written statement by Secretary of State for Health 25 March 2015 CELC0000002\_034

1394 Hansard parliamentary debate on the Penrose Inquiry 26 March 2015 p3 RLIT0001575

1395 Emphasis added. Hansard parliamentary debate on the Penrose Inquiry 26 March 2015 p3 RLIT0001575

1396 Historical Transmission of HIV/Hepatitis C via NHS-Supplied Blood and Blood Products: Key Issues and Upcoming Decisions 28 May 2015 p5 WITN0823012, Memo from Philippa Snape to Parliamentary Under-Secretary of State for Public Health 12 June 2015 pp2-4 RLIT0001917

*groups in 2009/09 (high risk groups include ex-intravenous drug users and members of the South Asian population)."*<sup>1397</sup>

It was thought that there were around 2,200 people who had been infected by transfusion or blood products who were unaware of this. The options were:

- "i. Option 1: Do Nothing.*
- ii. Option 2: Remind GPs of this issue and that they should offer HCV testing to those at risk via the GP Bulletin.*
- iii. Option 3: Contact all patients in England who received a blood transfusion before 1991.*
- iv. Option 4: Wider national HCV awareness campaign, subject to Cabinet Office agreement."*<sup>1398</sup>

The recommendation was Option 2. Its advantages were set out:

*"Writing to all GPs via the GP Bulletin and any other possible communications to highlight that there are potentially 2,200 unidentified individuals living in England with HCV as a result of receiving a blood transfusion between 1970-1991 and remind them of the 'Guidance for the prevention, testing, treatment and management of hepatitis C in primary care' (2007)<sup>1399</sup> which states that a HCV test should be offered to 'Recipients of blood (before 1991) or blood products (before 1986 in UK) and/or organ transplants (before 1992)' is likely to be affordable and could reduce the likelihood of those who are not at risk worrying unnecessarily or having unnecessary HCV tests, which will increase costs for the NHS ... This approach will not be particularly visible to the public, and you may face complaints from campaigners that more could be done to trace patients. You may therefore wish to combine this option with a small scale awareness raising campaign within healthcare settings."*<sup>1400</sup>

Jane Ellison accepted Option 2, and announced this to Parliament on 20 July 2015.<sup>1401</sup>

In doing so, she stated *"Lord Penrose made one recommendation: to take all reasonable steps to offer a hepatitis C test to everyone [in Scotland] who had a blood transfusion before September 1991 and who has not been tested for hepatitis C. In England, guidance to GPs has been issued over the years by the Department of Health, the NHS, and other health organisations which recommend that a hepatitis C test should be offered to patients who*

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1397 Memo from Philippa Snape to Parliamentary Under-Secretary of State for Public Health 12 June 2015 p8 RLIT0001917

1398 Memo from Philippa Snape to Parliamentary Under-Secretary of State for Public Health 12 June 2015 pp2-3 RLIT0001917

1399 Royal College of General Practitioners *Guidance for the prevention, testing, treatment and management of hepatitis C in primary care* 2007 NHSE0000135

1400 Memo from Philippa Snape to Parliamentary Under-Secretary of State for Public Health 12 June 2015 pp8-9 RLIT0001917

1401 House of Commons written statement by Parliamentary Under-Secretary of State for Public Health 20 July 2015 MACF0000022\_070

*received a blood transfusion in the UK before 1991 or were treated with blood products before 1986. This can currently be found on the NHS Choices website. In light of Lord Penrose’s recommendation, the Department will be acting to ensure that GPs are reminded of this duty.*<sup>1402</sup>

On 9 September she reported that GPs had been notified.<sup>1403</sup> They were notified by a “Regional Action Bulletin”. Although the Bulletin could have been clearer in defining the “date before” (it said in its headline point in respect of transfusions “*before 1991*”) in the paragraph immediately following it left little doubt that this was “*before September*”.<sup>1404</sup>

Unfortunately, there remained, uncorrected, the recommendation in the 2007 guidance, (quoted in the statement to Parliament) that testing of those who had received blood products before 1986 should be offered a test. It inferred that there was no appreciable risk after that date. However, most available blood products continued to transmit hepatitis throughout the 1980s – the only blood product which was free of the risk of transmitting Hepatitis C as from 1986 was 8Y, produced by the Blood Products Laboratory (“BPL”), in England. In Scotland a comparable NHS product was first universally available as from April 1987 and in both countries commercial blood products remained a risk. Though the principal aim was to test those who had received blood transfusions before universal screening was introduced, it is a pity that this “hole in the net” in respect of blood products was not firmly closed. I do not blame the Minister at all for this: it was the fault of whoever briefed the working party responsible for the guidance in 2007, the terms of which were simply repeated (so far as they concerned blood products) in her statement.

In Scotland, a working group was set up and made three recommendations:

- (a) A targeted public awareness campaign focused **solely** on people who received a transfusion before September 1991.
- (b) Writing to people who had received blood products but were not known to have been tested.
- (c) A CMO letter to remind all clinicians of risk factors including intravenous drug use and blood transfusions before September 1991, clinical indicators such as unexplained raised alanine transaminase (“ALT”) liver enzyme levels and to inform them about recent advances in treatment and thus the benefits of testing.<sup>1405</sup>

These recommendations were promptly accepted.<sup>1406</sup> In his evidence to the Inquiry, Professor John Dillon described the Penrose recommendation as “*ongoing*” and noted that the barrier to identifying those infected with hepatitis C via blood and blood products “*remains for those*

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1402 House of Commons written statement by Parliamentary Under-Secretary of State for Public Health 20 July 2015 MACF0000022\_070

1403 Hansard parliamentary debate on Contaminated Blood Products 9 September 2015 p7 RLIT0002233

1404 Regional Action Bulletin 3 September 2015 p4 RLIT0001916

1405 The Penrose Inquiry Recommendation: Report of a Scottish Government Commissioned Short-Life Working Group August 2016 pp23-24 WITN0713016

1406 Letter from Dr Catherine Calderwood to colleagues 20 September 2016 WITN5672003



*patients for whom there are no records of their blood transfusions and the individual patient is unaware of having had a blood transfusion or of the risks associated with this.*<sup>1407</sup>

## Commentary

The history recounted here is remarkable in a number of respects.

First, it is one where even before universal screening of donations was introduced there was considerable argument in favour of a lookback, for what were well-articulated reasons. The reasons for not starting a lookback sooner are thin – as will be described below – and difficult to fathom once universal screening was adopted.

Second, it is a story of a mixture of non-discussion and indecision, and an apparent desire to avoid having to bite the bullet of deciding to implement such screening for a mixture of two main reasons (as it seems to me) – first the cost and effort of doing so, and second the embarrassment.<sup>1408</sup> There was discomfort that there might be adverse comment or litigation if patients were told both that they might have been infected, but also that they might not have been. It would be awkward that they could not be told for sure what a positive test meant. There would inevitably be reaction to being told that the UK blood services were responsible for giving patients an infection, but that there was nothing that could be done to treat them. Even worse, little advice could be given except to avoid alcohol and be particularly careful in personal relationships; and that no-one could be exactly sure what the future was likely to hold except that the disease would probably be a long-term one.

Another remarkable feature is that the CMO, Dr Kenneth Calman, did not have any personal involvement in the issues surrounding lookback until November 1994, when a submission on this topic was sent to his Private Office (as a result of which he attended the ACVSB meeting in December and emphasised that the public interest required an urgent decision).<sup>1409</sup> Nor was any minister given to understand that whereas HIV screening had been accompanied by HIV lookback, its equivalent had not happened when Hepatitis C screening was introduced across the UK. Why, then, was lookback introduced when it was? There is no clear answer to this, but it seems plain that Dr Gillon's initiative in Scotland played a large part in showing that lookback would both work, and work well, and hence

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1407 Written Statement of Professor John Dillon para 5.2 WITN4062003

1408 This is underlined by the fact that decisive action was first taken at a time when the media were raising concerns about people having been infected through transfusions, and a minister had been invited to be interviewed by *Panorama*.

1409 He added: "*However, it is possible that I was kept informed of developments by Dr Metters at an earlier date*", though it is plain he has no actual recollection of this. Written Statement of Sir Kenneth Calman para 40.2 WITN3430001. This is not intended as a criticism of the CMO himself: the failure is that of the Department of Health to ensure that the CMO was fully briefed and involved.

had a major influence in what then took place across the UK.<sup>1410</sup> Media attention and the possibility of being sued played a part.<sup>1411</sup>

Fourth, the history demonstrates that it is often easy for an advisory body to avoid grasping the nettle by either marking it as a decision for later discussion by the same body, or by passing it over to another advisory committee – which might then itself avoid grasping that same nettle. The history supports a conclusion that having a number of advisory bodies considering the same question(s) is to be avoided, since it tends to create a paralysis of decision-making. The decision-making is, by definition, not that of an advisory committee – but if a minister is to take definitive action that minister is likely to want to be clear as to the advice they are being given. Where there is no advice as yet – because views on the issue are bobbing to and fro between different advisory bodies without any final clear steer – the minister will not have the clarity of advice which is desirable.

Fifth is that one part of the UK – Scotland – was thwarted in taking a lead in introducing lookback at an early stage (though Dr Gillon, in a principled stand, managed to do so in Edinburgh and the South East). The ponderous approach of the Department of Health was essentially responsible for this – as was the view that for one region or part of the UK to introduce a step which might benefit patients ahead of other regions might expose those other regions to litigation at a later date. The answer to that can be colloquially put as “So what?” – if a measure will protect patients, it will do so in whichever area it is introduced. Deliberately to delay its introduction in one area to await others to catch up is not to prioritise the protection of patients, but rather to work to the lowest common denominator – the pace of the slowest – and thereby prejudice the protection of patients in those areas ready to introduce the measure earlier.

But sixth is that the patient perspective – in particular their safety and autonomy – featured so little. Dr Robinson, medical director of the NBA from 1994 to 2005, having reflected on the events described above, told the Inquiry that the various committees which considered lookback “took a very scientific view of events, separate from what was happening to patients.” She stated that this is an important lesson and that she was very sorry that this was the case.<sup>1412</sup>

A lack of patient focus is fundamental to the issues here. A person who had received infected blood had a right to know of this so they could take decisions about their life, which were for them and not health professionals to make. They had a right to know whether or not treatment was available for them. Moreover there was a lost opportunity for them to take

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1410 Dr Rejman said of this: “*I think the reasons why the look-back was started when it was, was first of all, by that stage, we were more certain of the tests and the validity of the tests. Probably the crucial points were that the feasibility of a look-back had been demonstrated because in Scotland ... they could actually say that it should probably work and work well. And also about this time we had a licensed treatment for hepatitis C.*” Dr Andrzej Rejman Transcript 11 May 2022 pp155-156 INQY1000204

1411 See above. The NBTS(Wales) briefing note gave the *Panorama* programme due to cover the issue in January 1995 as one of four reasons for “*lookback now*”. Note from F Williams of NBTS (Wales) on HCV lookback 26 January 1995 p2 WBSV0002875

1412 Written Statement of Dr Angela Robinson para 629 WITN6926003

simple lifestyle measures that may have improved their prognosis – for example by ceasing to drink alcohol; or by changing diet. For those people who were persistently unwell, it would have given them clarity as to what was causing this and reassured them that they were not hypochondriac. They needed to know, too, so that they were in a position where they could both avoid harming others, and second be able to tell any others they wished of their condition and its cause so that those others might better understand it.

Seven reasons for not introducing lookback at or around the same time as universal screening were identified above.<sup>1413</sup> They are specious because:

- (a) The fear that a patient may sue if told that the actions of the health service may have harmed them<sup>1414</sup> may be real, but it is not a proper reason for not telling. It is, instead, disgraceful that a patient should not be told the truth because it might be harmful to the financial or reputational interests of a professional person or body who/which has caused them harm.
- (b) The significance of universal screening was that donors would have, ethically, to be told that their donations were not being used and why. It led inexorably to having to counsel donors. In essence, counselling donors identified on lookback was no different.
- (c) It being too early because tests were at early stage was no longer relevant when tests had evolved as far as being introduced universally across the UK.
- (d) The health service exists to provide, at public cost, for the treatment of those who need it. Identifying people in need is a necessary and integral part of its functions. In short, to adopt shortage of funding as a reason is deliberately to leave untreated a part of the population which is ill.
- (e) The absence of treatment was a fact at the time: but telling people of their infection was nonetheless ethically mandated: it allowed a person to take advantage of treatments if and when they became available, but more importantly to take their own decisions as to what was best for them in terms of diet, alcohol, intimate personal relationships, and what best to avoid doing. It allowed them to plan their life with a better knowledge of their circumstances. Essentially, it respected their autonomy. Not telling them denied this.
- (f) To be concerned that patients might become distressed was unjustified paternalism. Moreover, the argument did not contemplate the flipside: the distress there might be (and in the event was) when individuals found out they had tested positive, and been infected, some time after a test on their blood had been conducted. Their reaction of distress and anger at knowing some time after others knew and had not

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1413 In the section of this chapter: *Why wasn't a national Hepatitis C lookback started earlier?*

1414 As set out in the section headed *Consideration in 1989* this was a view expressed in 1989 by Dr Lee, and echoed by the legal advisor to the North Western Regional Health Authority, as a reason not to proceed with lookback. It is not otherwise articulated in recorded discussions, but must be regarded as a reason for the North West RHA opposing lookback at the time.

told was at least as powerful as any distress from knowing, and most probably well in excess of it.

- (g) The belief of some clinicians that patients might be better not knowing is again paternalistic. The advantages of knowing of one's condition outweighed it: there may be a few, truly exceptional cases, where this might not be so but that is no basis for refusing to adopt a general policy of being open and transparent.
- (h) A lack of reliability of the test is no more a basis for rejecting lookback than it was for not screening donations in the first place.

In summary, there is no reason against lookback which stands scrutiny.

Lookback should have begun around the time that universal screening was introduced. The systems were then in place to cope with testing, confirmatory testing, and counselling. Patients and their overall protection should have had priority. They did not: instead, there was unnecessary delay, which ultimately meant that harm was done. A number of people whose infections could and would have been diagnosed were left in ignorance, at least for a while longer, and some may have continued potentially to expose others to risk.

There was no adequate basis for distinguishing Hepatitis C and HIV infections when it came to lookback. The latter began almost immediately there was universal screening. Sadly, and wrongly, the former did not.

The responsibility for this delay lies centrally on the Government. The Department of Health and the blood service in England/the NBA were principally responsible, and the SHHD (until the second half of 1994), the Welsh Office and the Northern Ireland Office might be forgiven for following their lead – though with a concern for public health in their own nation could and probably should have pressed central government to resolve the paralysis of decision-making that has characterised this account.

The final submissions of SNBTS and NIBTS demonstrate that both felt unable to make the progress they might have wished without a decision by the Department of Health to take action. SNBTS said: "*The principle of tracing recipients of potentially infectious blood had been established by the precedent of introducing lookback at the time of commencing screening for HIV in 1985*" – but that it would have been very difficult for them to progress this unilaterally.<sup>1415</sup> NIBTS quoted Dr Morris McClelland saying "*we would have been very keen to get on with doing this, in the same way as we had been doing with HIV*" but "*we had to await a departmental decision*".<sup>1416</sup> The Welsh Blood Service do not address the issue in their submissions, but it is to be inferred that NBTS (Wales) would have found it very difficult to differ from England's lead. The national blood services (apart from the blood service in England/the NBA) are thus not the focus of this criticism.

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1415 Written submission of National Services Scotland and SNBTS para 141 SUBS0000044

1416 Written submission of Northern Ireland Blood Transfusion Service para 41 SUBS0000051, Dr Morris McClelland Transcript 1 February 2022 p145 INQY1000179

## 5.8 Public Health

This chapter considers the public health structures in the UK, including the systems for communicable disease surveillance, and how they changed over time.

### Key dates

**1946** PHLS is established.

**1948** creation of the NHS.

**1968** Working Party on Haemodialysis Units report is published.

**1968** Hepatitis becomes notifiable disease.

**1969** CDSU established.

**1972** Rosenheim Committee report on hepatitis outbreaks in renal units is published.

**1974** reorganisation of the NHS including abolition of the Medical Officer of Health role.

**1977** CDSC is established.

**1988** Acheson report *Future Development of the Public Health Function* is published.

**2002** Donaldson report *Getting Ahead of the Curve* is published.

### People

**Sir Donald Acheson** Chief Medical Officer (1983 - 1991)

**Sir Liam Donaldson** Chief Medical Officer (1998 - 2010)

**Dr Spence Galbraith** director, Communicable Disease Surveillance Centre

### Abbreviations

**CDSC** Communicable Disease Surveillance Centre

**CDSU** Communicable Diseases (Scotland) Unit

**ERL** Epidemiological Research Laboratory

**MOH** Medical Officer of Health

**PHLS** Public Health Laboratory Service



Health may mean different things to different people. For some, it is freedom from disease. For others it is being able to live a long life, well. For some it is a state of well-being, in every aspect of life, not only physically but mentally. It may lead many to adopt a “healthy diet”, or to exercise, or to give up (or never start) smoking.

In 1871, the Royal Sanitary Commission described how important “**public**” health was. It said “*The importance of the subject cannot be too highly estimated. The constant relation between the health and vigour of the people and the welfare and commercial prosperity of the State requires no argument. Franklin’s aphorism, ‘public health is public wealth,’ is undeniable.*”<sup>1417</sup>

Over a hundred years later, another Committee of Inquiry – considering the future development of public health – repeated those words. Two outbreaks of communicable disease in 1984 and 1985, one of salmonella food poisoning in a hospital in Wakefield (August 1984), and one of Legionnaires’ disease at Stafford (April 1985), had each resulted in public inquiries which had pointed to a decline in the investigation and control of communicable diseases. There was concern, too, about the future role of community medicine. The Secretary of State for Health and Social Services therefore set up a third inquiry, in January 1986. It had a broader remit, which was to “*consider the future development of the public health function, including the control of communicable diseases and the specialty of community medicine, following the introduction of general management into the Hospital and Community Health Services*”.<sup>1418</sup> The Chief Medical Officer (“CMO”), Sir Donald Acheson, chaired it.

Although it is something of an aside here, it should not pass without mention that elsewhere in this Report the continued refusal to hold a public inquiry into the illnesses resulting from infected blood and blood products is discussed.<sup>1419</sup> It may seem ironic<sup>1420</sup> that the 1986 Committee of Inquiry described in the foregoing paragraph was in effect a third public inquiry within two years into two highly localised outbreaks of disease, which had come to light at very much the same time as deadly infections had become known to have been transmitted by blood over the whole country, yet there was no public inquiry then, or for another 30 years,<sup>1421</sup> into transmission of HIV or hepatitis through blood or blood products. It is also a matter of some surprise that it was not outbreaks of AIDS which caused the commission of inquiry to be called.<sup>1422</sup>

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1417 Emphasis added. Public Health in England: The Report of the Committee of Inquiry Into the Future Development of the Public Health Function January 1988 p3 RLIT0001743

1418 Public Health in England: The Report of the Committee of Inquiry Into the Future Development of the Public Health Function January 1988 p5 RLIT0001743

1419 See the chapter on *Delay in Holding a Public Inquiry*.

1420 And curious. And tragic.

1421 22 years in the case of Scotland (Penrose Inquiry); 31 years for the UK as a whole (Infected Blood Inquiry).

1422 There was, however, some mention of AIDS in four paragraphs where it was singled “*out for special mention*”. The context was societal transmission, and sexually transmitted disease. Public Health in England: The Report of the Committee of Inquiry Into the Future Development of the Public Health Function January 1988 pp51-52 RLIT0001743. An explanation for it not being part of the reasons given for the 1986 Committee of Inquiry may be that at the time it may have been thought too early

The Committee of Inquiry chaired by Sir Donald Acheson started by asking what “*public health*” meant. Its answer was “*the science and art of preventing disease, prolonging life and promoting health through organised efforts of society.*”<sup>1423</sup> It had the prevention of communicable disease, as part of that, in particular focus.

Whichever of various definitions is adopted, public health is not a new concept.

*“A key period for public health came with the rise of the ‘modern state’ in the 19th century. Rapid economic growth and mass urbanization coincided with high mortality from infectious diseases such as cholera and typhus. Increases in life expectancy in the late 18th century juddered to a halt until the 1870s because of unhealthy urban environments. The definition and compass of public health at this time was about drains and sanitation, cleansing the environment as a whole. But this focus for public health changed during the century. Scientific breakthroughs in the 1860s, when the French chemist Louis Pasteur formulated germ theory, brought vaccines and pharmacotherapy for specific diseases. The environmental emphasis of 19th-century public health gave way to a greater focus on the individual, to education and personal advice”*.<sup>1424</sup>

Organised public health in England and Wales began in the middle of the nineteenth century with the passing of the first Public Health Act in 1848. This Act provided for the establishment of a General Board of Health and of Local Boards of Health, and empowered the latter to appoint a medical officer of health (“MOH”).<sup>1425</sup> In 1855 the first CMO, Dr John Simon, was appointed; in 1857 he published the first public health annual report. The first MOH for Cardiff was appointed in 1855 and the first MOH for Edinburgh in 1862.<sup>1426</sup> In 1871 a Local Government Board was established, with a public health department which assumed responsibility for sanitary and public health. Various powers and duties relating to sanitation and to infectious diseases were conferred on local authorities by the Public Health Acts of 1872<sup>1427</sup> and 1875. Public health remained under local control for the next hundred years or so.

It became evident in the nineteenth century that effective interventions were dependent on the reporting of accurate information. The Infectious Disease (Notification) Act 1889 required a doctor treating a patient with a “notifiable” disease to inform the MOH forthwith.<sup>1428</sup>

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for lessons to be learned, since the country was still in the throes of fighting HIV infection as a current epidemic.

1423 Public Health in England: The Report of the Committee of Inquiry Into the Future Development of the Public Health Function January 1988 p5 RLIT0001743

1424 Berridge *Public Health: A Very Short Introduction* 2016 p2 RLIT0002332. Suggested further reading: chapter titled *The origins of public health into the 1700s* of the same text.

1425 Galbraith and Young *Communicable disease control: the development of a laboratory associated national epidemiological service in England and Wales* Community Medicine 1980 WITN7123003

1426 Respectively Dr Henry Payne and Sir Henry Littlejohn. The first MOH for Glasgow was appointed in 1872.

1427 The 1872 Act made the appointment of a MOH in urban areas compulsory.

1428 Notifiable diseases included smallpox, cholera, diphtheria and typhoid. Infectious Disease (Notification) Act 1889 section 6 p3 RLIT0002276

Notification was a first step, not the whole story. What was notified to the MOH needed professional analysis to understand fully its implications. Notification would enable the MOH to investigate the infection's origin and, if needed, take measures to limit its spread. The MOH was a medical appointment, of people capable of the necessary analysis and applying the understanding that came with medical education and experience.

The Ministry of Health Act 1919 established the Ministry of Health,<sup>1429</sup> which replaced the Local Government Board. The Ministry had oversight over all environmental factors influencing public health. The Minister's duty was *"to take all such steps as may be desirable to secure the preparation, effective carrying out and co-ordination of measures conducive to the health of the people"*, including *"measures for the prevention and cure of diseases"*, *"the initiation and direction of research"* and *"the collection, preparation, publication, and dissemination of information and statistics relating thereto"*.<sup>1430</sup> Municipal authorities' health roles expanded, to include the provision of infectious disease hospitals, general hospitals and personal health services for vulnerable patient groups and dealing with specific diseases.<sup>1431</sup>

The creation of the National Health Service ("NHS") in 1948 significantly altered the public health structure. Described as a tripartite structure, responsibilities for public health ranged across three parts: local authorities, hospital boards and general practitioner services. The MOH role remained with local authorities and MOHs retained responsibilities for communicable disease control and environmental health. They were highly regarded, and had executive powers in their field. Hospital boards oversaw hospital care and had their own senior administrative medical officers ("SAMOs") who acted as chief medical officers to the regional hospital boards and were responsible for medical advice on the planning and development of clinical services.<sup>1432</sup>

Sir Donald Acheson's Committee of Inquiry into the Future Development of the Public Health Function, when it reported in 1988, described it as *"ironic that the year 1948, which is usually viewed without reservation as the date in which a new era dawned for the health of the nation, was the year in which separation of much of the public health function from the rest of the NHS sowed the seeds of a confusion of roles between local authorities and health authorities"*.<sup>1433</sup>

General practitioner services were the responsibility of executive councils and they began to play an increasingly important role in prevention and health promotion, sharing responsibility with services provided by the local authority, although again the Acheson Committee of Inquiry noted that *"The divided responsibility led to problems of co-ordination and difficulty in*

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1429 In 1968 the functions of the Ministry of Health transferred to the new Department of Health and Social Security.

1430 Ministry of Health Act 1919 section 2 p1 RLIT0002278

1431 Public Health in England: The Report of the Committee of Inquiry Into the Future Development of the Public Health Function January 1988 p8 RLIT0001743

1432 Public Health in England: The Report of the Committee of Inquiry Into the Future Development of the Public Health Function January 1988 pp8-9 RLIT0001743

1433 Public Health in England: The Report of the Committee of Inquiry Into the Future Development of the Public Health Function January 1988 p9 RLIT0001743

*ensuring coverage of the whole population which persisted through the 1974 reorganisation and which have still not been fully resolved.”<sup>1434</sup>*

The history of the immediate post-war period was one in which the threats posed by endemic disease, and outbreaks of infection, seemed to diminish. A combination of new drugs, and vaccination, led to the perception that public health control of communicable disease was of diminishing importance, and there was instead a growing emphasis on prevention of illness by lifestyle. As Professor David Armstrong put it in evidence:

*“During the ’70s, ’80s and ’90s ... we thought infectious diseases had been removed as a major threat. There was a phenomenon called the epidemiological transition which was promoted in the 1970s, taught to all medical students, that in fact we’d moved from an era of lots of infectious diseases, like tuberculosis, to ones of lifestyle-related disease, which were cancer and cardiovascular disease. So medicine thought it had won because TB had virtually disappeared, vaccinations, antibiotics, and everything, seemed to remove infectious disease. There seemed to be a little bit of interest in infectious disease in other countries because in tropical Africa there were various things, like malaria, and so on, which were still of interest, but there was no great interest in medicine in infectious diseases for that 30-year period. I think, as we picked up here, that one or two voices began at the very beginning of the 21st century, to say ‘Hey, this is important, this could come back and hit us.’ But I think broadly medicine took its eye off the ball during those decades.”<sup>1435</sup>*

The director of the Public Health Laboratory Service (“PHLS”), Sir James Howie, was already concerned in 1969 that MOHs no longer had *“the skills, experience and training, or the time, for adequate infectious disease control.”<sup>1436</sup>*

A substantial reorganisation of the NHS took place in 1974 following the enactment of the National Health Service Reorganisation Act 1973. In this 1974 reorganisation, health functions were transferred away from local authorities, moving to regional and area health authorities and health boards in Scotland.<sup>1437</sup> Local authorities retained oversight for environmental health and social services.<sup>1438</sup>

The transitional guidance issued by the Department of Health and Social Security (“DHSS”) in 1973 at the time of enactment of the new legislation outlined the new, joint working

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1434 Public Health in England: The Report of the Committee of Inquiry Into the Future Development of the Public Health Function January 1988 p9 RLIT0001743

1435 (Professor David Armstrong) Public Health and Administration Expert Panel Transcript 3 October 2022 p85 INQY1000251. Professor Armstrong is professor of medicine and sociology at King’s College London.

1436 Supplementary Expert Report to the Infected Blood Inquiry: Structures and Funding of the Communicable Disease Control System in England 15 November 2022 pp10-11 EXPG0000129, Howie *Training of epidemiologists for control of communicable diseases* Proceedings of the Royal Society of Medicine 1970 (for a meeting in 1969) pp1-2 RLIT0002282

1437 The tasks of executive councils shifted to family practitioner committees.

1438 Public Health in England: The Report of the Committee of Inquiry Into the Future Development of the Public Health Function January 1988 pp9-10 RLIT0001743

arrangements, roles, and responsibilities. The newly established regional and area health authorities in England and Wales, and health boards in Scotland, were to be responsible for a range of services contributing to the prevention, control and treatment of communicable disease.<sup>1439</sup> The statutory powers for communicable disease control, however, remained with the local authorities, although these were “*with weakened capacity and complex working arrangements with new health authorities.*”<sup>1440</sup>

It has been suggested that “*the loss of the Medical Officer of Health was a grave strategic error, because he was a person of importance, influence, with substantial independence in the local authority and he was powerful ... The public health voice was weakened by this reorganisation.*”<sup>1441</sup>

The position of the MOH ceased to exist but in many areas the responsibilities they had had were taken up by community physicians. This was a new role, executed vigorously in some parts of the country, contributing to the planning and development of local health services, but not in others.<sup>1442</sup> Community physicians assumed a dual role, serving part-time as medical consultants to local authorities, receiving disease notifications. This restructuring resulted in local authorities losing their dedicated medical divisions, retaining only a singular, part-time medical officer. No doubt mindful of the need to maintain a link between local authorities exercising health functions, and regional health authorities, the guidance advised local authorities to appoint a doctor who would also be a community physician of the health authority, to be known as the medical officer of environmental health (“MOEH”), as “*proper officer*” to enable them to effectively discharge their communicable disease control duties.<sup>1443</sup>

The Expert Report to the Inquiry on Public Health and Administration summed up the effect on public health functions in this way:

*“Until 1974 local authorities employed medical officers of health (MOHs) with their own departments. They were medically trained, had substantial expertise, received disease notifications, and exercised executive powers. They were abolished in 1974 when both local government and the NHS underwent significant simultaneous reorganisations, at a time when the government considered that the ‘main infectious diseases which were once the major cause of death of people of working age have been virtually eliminated as health problems’ (Department of Health and Social Security, 1970).”*<sup>1444</sup>

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1439 DHSS NHS Reorganisation Circular October 1973 DHSC6887705

1440 Expert Report to the Infected Blood Inquiry: Public Health and Administration August 2022 p14 EXPG0000048

1441 (Professor Brian Edwards) The 1974 NHS Reorganisation Witness Seminar Transcript 9 November 2016 pp44-45 ULIV0000001. Professor Brian Edwards held various positions in area and regional health authorities and at the time of the seminar was professor of health services management at the University of Nottingham.

1442 Public Health in England: The Report of the Committee of Inquiry Into the Future Development of the Public Health Function January 1988 pp10-11 RLIT0001743

1443 DHSS NHS Reorganisation Circular October 1973 DHSC6887705

1444 Expert Report to the Infected Blood Inquiry: Public Health and Administration August 2022 p14 EXPG0000048, DHSS *The Future Structure of the National Health Service* 1970 RLIT0002293



## The Acheson Report 1988

High-profile communicable disease control failures in the 1980s – the 1984 salmonella outbreak at Stanley Royd Hospital and the 1985 Legionnaires’ disease outbreak in Stafford – spurred the formation of the Committee of Inquiry into the Future Development of the Public Health Function, chaired by CMO Sir Donald Acheson, as described at the start of this chapter. The Acheson Report noted that both the events leading up to its establishment and the AIDS epidemic “*remind us of the crucial continuing need for an effective system for the prevention, surveillance and control of communicable disease and infection.*”<sup>1445</sup> It identified key problems that emerged after 1974: unclear statutory responsibilities, ineffective cooperation between health and local authorities, divided accountability and other issues within the office of the MOEH, and a general confusion about roles and responsibilities.<sup>1446</sup> The report found a “*set of measures which have evolved over and which taken together, have created a system which is complicated and at times unclear, even to those who have to operate it. To others it can be positively baffling.*”<sup>1447</sup>

The Acheson Report recommended that the office of the MOEH should be abolished and that the post of district control of infection officer be established as the named individual responsible for control of communicable disease and accountable to the director of public health, and that the postholder would be medically qualified and “*have the necessary expertise in subjects related to control of communicable disease and infection.*” They would normally be a consultant in public health medicine, and the report recommended that 50 additional consultant posts be established across the country.<sup>1448</sup>

The report also clarified that health authorities were primarily responsible for most communicable diseases, with local authorities handling food and waterborne diseases.<sup>1449</sup> Subsequently, Circular HC(88)64 advised health authorities to appoint both a director of public health and a consultant for communicable disease control, while also reinforcing hospital roles in infection control and empowering proper officers to conduct investigations.<sup>1450</sup>

During the 1990s, the public health focus shifted from clinical epidemiology, communicable disease control and medical administration to broader societal health issues like lifestyle and education.<sup>1451</sup>

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1445 Public Health in England: The Report of the Committee of Inquiry Into the Future Development of the Public Health Function January 1988 p6 RLIT0001743

1446 Public Health in England: The Report of the Committee of Inquiry Into the Future Development of the Public Health Function January 1988 pp24-25 RLIT0001743

1447 Public Health in England: The Report of the Committee of Inquiry Into the Future Development of the Public Health Function January 1988 p43 RLIT0001743

1448 Public Health in England: The Report of the Committee of Inquiry Into the Future Development of the Public Health Function January 1988 pp49-51, p42 RLIT0001743

1449 Public Health in England: The Report of the Committee of Inquiry Into the Future Development of the Public Health Function January 1988 p49 RLIT0001743

1450 Department of Health *Health of the Population: Responsibilities of Health Authorities* December 1988 DHSC0004455\_049

1451 Expert Report to the Infected Blood Inquiry: Public Health and Administration August 2022 p15 EXPG0000048

## The Donaldson Report 2002

Less than 15 years after a former CMO (of England) had reported on the future of the public health function, another CMO went to press on the same topic, though with an even greater focus on communicable disease prevention. The opening words of the executive summary of Sir Liam Donaldson's report *Getting Ahead of the Curve: A strategy for combating infectious diseases* express the view that the basis on which the 1974 reforms had been made had been mistaken, at least so far as communicable disease control was concerned: "*Infectious diseases have been a threat to people's survival, health and well-being since human life began. Post-war optimism that their conquest was near has proved dramatically unfounded.*"<sup>1452</sup>

He went on to say: "*One important issue is the scale of emergence of new or previously unrecognised infectious diseases. Since the early 1970s at least 30 previously unknown infectious diseases have become prominent, for which there is no fully effective treatment. Infectious diseases recognise no international boundaries, so that a newly emergent disease in another part of the world must be assessed as a potential threat to this country.*" Of the infectious diseases which had emerged in the previous 30 years, three had been a major cause of illness and death – HIV, Ebola (so far limited to a small number of areas in the world) and vCJD. He spoke presciently, in words with particular resonance for us some 20 years later, of the major influenza pandemic of 1918-19, in which around 228,000 people in Britain had died, saying: "*Most experts believe that it is not a question of whether there will be another severe influenza pandemic but when*"; that "*It is essential to expect the unexpected*" and that "*Good surveillance, early assessment of potential problems and strong contingency plans are clearly essential if we are to recognise them early and respond efficiently to minimise their impact.*"<sup>1453</sup>

His proposals led to the establishment of the Health Protection Agency in 2003.<sup>1454</sup>

## The roles and responsibilities of the Public Health Laboratory Service

The Public Health Laboratory Service ("PHLS") was established under the National Health Service Act 1946, and succeeded the Emergency PHLS, which was set up in 1939. One of the main reasons for the creation of the Emergency PHLS was "*to provide a national laboratory service for the rapid detection of incidents of infectious disease, especially*

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1452 The report stated that "*Although this country is respected internationally for its work on infectious disease surveillance, the present system falls short of what is necessary fully to protect the public health*" and that "*There is no formal point of co-ordination for the many separate infectious disease surveillance systems.*" Department of Health *Getting Ahead of the Curve: A strategy for combating infectious diseases (including other aspects of health protection)* 10 January 2002 p9, p12 DHSC5017529. See also Written Statement of Sir Liam Donaldson para 56.1 WITN7557001

1453 Department of Health *Getting Ahead of the Curve: A strategy for combating infectious diseases (including other aspects of health protection)* 10 January 2002 pp10-11 DHSC5017529

1454 Expert Report to the Infected Blood Inquiry: Public Health and Administration August 2022 p15 EXPG0000048

*those geographically widespread, so that prompt investigation could take place and control measures implemented.*<sup>1455</sup>

The function of the PHLS was “to provide a bacteriological service, which may include the provision of laboratories, for the control of infectious diseases”.<sup>1456</sup> PHLS was overseen by the Medical Research Council (“MRC”) until the Public Service Laboratory Act of 1960 after which responsibility was transferred to a new PHLS Board that was accountable to the Minister of Health.<sup>1457</sup>

The board included individuals from varied backgrounds, including those nominated in conjunction with the MRC, bacteriologists, medical officers of health, hospital representatives, and general medical practitioners.<sup>1458</sup> Between 1985 and 1992 the board membership of PHLS included a deputy chief medical officer from the Department of Health and until 1989 a deputy chief medical officer from the Welsh Office.<sup>1459</sup>

In the late 1970s the PHLS Board’s responsibilities were extended to include the management of the Centre for Applied Microbiology and Research at Porton Down,<sup>1460</sup> which was formerly the Microbiological Research Establishment of the Ministry of Defence.<sup>1461</sup> PHLS was linked with NHS hospital diagnostic laboratory services and provided advice and assistance to local public health officials, including a bacteriology and virology service.<sup>1462</sup>

## Laboratory network

The PHLS managed an extensive network of laboratories across England and Wales, with the headquarters in Colindale housing the Central Public Health Laboratory. This facility was not just an administrative centre: it was the heart of the PHLS’s scientific endeavours. The Central Public Health Laboratory housed specialist and reference laboratories, which were organised into divisions focusing on critical areas like enteric pathogens, hospital infection, microbiological reagents and quality control, food hygiene, virology reference, and the national collection of type cultures.<sup>1463</sup>

The PHLS network comprised regional and area laboratories, commonly referred to as peripheral laboratories. These laboratories, mostly located in hospitals, were run in conjunction with NHS hospital laboratories. While the PHLS and hospital laboratories shared common goals in diagnostics and patient care, the PHLS laboratories had the added

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1455 Galbraith *A Review of the PHLS Communicable Disease Surveillance Centre* January 1986 p3 PHEN0001261

1456 National Health Service Act 1946 section 17 p23 RLIT0002280

1457 Extract from the PHLS Annual Report 1985/1986 p1 ARCH0000727. See also: Howie *The Public Health Laboratory Service* The Lancet 1965 RLIT0001746

1458 Public Health Laboratory Service Act 1960 section 3 Schedule p4 RLIT0002281

1459 Written Statement of Sir Joseph Smith to the BSE Inquiry 16 October 1988 p2 BSEI0000012

1460 Written Statement of Dr Robert Kyffin para 2.4 WITN7123001

1461 Written Statement of Sir Joseph Smith to the BSE Inquiry 16 October 1988 para 5 BSEI0000012

1462 Howie *The Public Health Laboratory Service* The Lancet 1965 p1 RLIT0001746

1463 PHLS Functions And Objectives pp1-4 MRCO0000018\_020

responsibility of fulfilling public health functions. This included providing countrywide support to local authority and health authority medical officers and environmental health officers.<sup>1464</sup>

While laboratory services were considered to be highly effective, health protection services in England suffered from inadequate national coordination.<sup>1465</sup>

### **Epidemiological research and surveillance**

Central to the PHLS's epidemiological research efforts was the Epidemiological Research Laboratory ("ERL") created in 1946. The ERL undertook the analysis and interpretation of centrally collected laboratory data.<sup>1466</sup> It also organised and carried out epidemiological surveys and field trials of vaccines and assisted in the organisation, coordination and investigation of disease in field studies, often in collaboration with PHLS laboratories, health authorities, industrial or university researchers, and family doctors.<sup>1467</sup>

It was closely linked with the National Institute for Biological Standards and Control and the Committee on Safety of Medicines, and was represented on various DHSS and MRC committees concerned with immunisation.<sup>1468</sup> It thus contributed to policies and practices in vaccine administration and safety across the UK.

A weekly summary report of infections identified by the PHLS laboratories was published from about 1940. In the 1950s this grew to include reports from non-PHLS laboratories, which became the Communicable Disease Report from 1967. These reports provided epidemiological oversight of infectious diseases in England and Wales.<sup>1469</sup> The reports included tabulated data on infections, accounts of epidemics, and analysis and reviews of epidemiological situations.<sup>1470</sup>

There was, however, no central function for communicable disease control, other than disease notification, until the establishment of the Communicable Disease Surveillance Centre ("CDSC") within the PHLS in 1977.

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1464 Fact Sheet On The Public Health Laboratory Service June 1996 pp3-4 DHSC0046944\_006

1465 Galbraith *A national public health service* Journal of the Royal Society of Medicine January 1981 p5 RLIT0001747

1466 Galbraith *A Review of the PHLS Communicable Disease Surveillance Centre* January 1986 p3 PHEN0001261

1467 Epidemiological Research Laboratory 20 October 1982 p1 PHEN0002504

1468 Epidemiological Research Laboratory 20 October 1982 p1 PHEN0002504

1469 Written Statement of Dr Robert Kyffin para 2.22 WITN7123001

1470 Communicable Disease Report 27 August 1982 RLIT0002181, Communicable Disease Report 11 March 1983 NHBT0052365, Communicable Disease Report 11 September 1992 DHSC0020767\_031

## Communicable Disease Surveillance Centre

The CDSC of the Public Health Laboratory Service was set up on 1 January 1977 to provide epidemiological assistance and coordination in communicable disease control for public health authorities in England and Wales.<sup>1471</sup>

Following a smallpox outbreak in London in 1973, and the subsequent Committee of Inquiry into the outbreak, the CDSC was established to improve coordination of health protection services across England. Despite the efficacy of laboratory services, according to Dr Spence Galbraith's retrospective paper there had been gaps in the coordination of health protection services across England and Wales, one of which was the absence of a centralised function specifically for communicable disease control until 1977.<sup>1472</sup>

On 1 November 1977 the CDSC assumed responsibility on behalf of the CMOs of the DHSS and Welsh Office for national advice, assistance and coordination in communicable disease control formerly provided by medical officers of DHSS,<sup>1473</sup> in turn increasing "*the epidemiological role of PHLS from primarily one of epidemiological intelligence to a greater involvement in active disease control*".<sup>1474</sup> Limited additional funding of £40,000 per year was made available to PHLS to cover the costs of these new functions.<sup>1475</sup>

The CDSC reported to, and liaised with the International Health, Microbiology of Food and the Environment and Communicable Disease ("Med IMCD") division of the DHSS, which was responsible for the monitoring of infectious and communicable diseases. These included diseases transmitted via blood transfusion and other blood products.<sup>1476</sup>

The main functions of the CDSC were:

### **"Surveillance and Control of Outbreaks**

- a. *CDSC exercises responsibility on behalf of the Chief Medical Officers (of the Department of Health and Social Security and the Welsh Office) for those duties relating to surveillance and advice on control of outbreaks which were formerly undertaken by medical officers in DHSS, except for International Health aspects which will remain with DHSS ... It responds to requests for advice, in collaboration with PHLS and hospital laboratories, co-ordinates control measures in an outbreak involving a*

1471 Galbraith and Young *Communicable disease control: the development of a laboratory associated national epidemiological service in England and Wales* Community Medicine 1980 p1 WITN7123003

1472 Galbraith *A national public health service* Journal of the Royal Society of Medicine January 1981 pp3-4 RLIT0001747, Galbraith *A Review of the PHLS Communicable Disease Surveillance Centre* January 1986 pp3-4 PHEN0001261

1473 Galbraith and Young *Communicable disease control: the development of a laboratory associated national epidemiological service in England and Wales* Community Medicine 1980 p2 WITN7123003

1474 Galbraith *A Review of the PHLS Communicable Disease Surveillance Centre* January 1986 p4 PHEN0001261

1475 Galbraith *A Review of the PHLS Communicable Disease Surveillance Centre* January 1986 p4 PHEN0001261

1476 Written Statement of Dr Diana Walford paras 2.31-2.32 WITN4461001



*number of districts, and is able to give assistance to MOsEH [medical officers of environmental health] particularly in serious incidents.*

### **Information**

- b. CDSC compiles and distributes the Communicable Disease Report (CDR) as part of a comprehensive information service for communicable diseases. The Centre is also responsible for the informal exchange and dissemination of epidemiological information on communicable diseases ...*

### **Teaching**

- c. CDSC participates in training programmes for community physicians and others involved in the control of communicable disease.”<sup>1477</sup>*

By 1980, the CDSC’s team included four consultant medical staff, information officers, medical trainees and administrative staff. Regional epidemiology roles were introduced in the 1980s, overcoming initial resistance dating back to the 1950s. These posts, jointly appointed between regions and the CDSC, added a regional component to communicable disease control. Professor Stephen Palmer took up a post in Wales in 1983 as consultant epidemiologist. When he did so, he was the only CDSC consultant epidemiologist in the regions and the first to be appointed through the CDSC training programme.<sup>1478</sup>

In 1984, CDSC moved to a new site at Colindale and merged with the PHLS Epidemiological Research Laboratory, expanding its functions to include research on vaccine-preventable diseases.<sup>1479</sup> The ERL integrated with the CDSC to form a new Division of Epidemiology headed by Dr Galbraith.<sup>1480</sup>

## **Northern Ireland, Scotland and Wales**

At different times distinct administrative arrangements were implemented in Northern Ireland, Scotland, and Wales.

### **Northern Ireland**

The overarching oversight of health systems was managed by the government, while the daily management was assigned to specific statutory bodies like the Northern Ireland General Health Services Board and the Northern Ireland Hospitals Board, which also owned

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1477 DHSS Health and Local Authority Circulars *Co-ordination of Epidemiological Services for Communicable Diseases and Food Poisoning: Communicable Disease Surveillance Centre* February 1980 RLIT0001622

1478 Written Statement of Professor Stephen Palmer para 5.1 WITN7654001, Galbraith *A Review of the PHLS Communicable Disease Surveillance Centre* January 1986 pp3-4 PHEN0001261

1479 Galbraith *A Review of the PHLS Communicable Disease Surveillance Centre* January 1986 p4 PHEN0001261

1480 Minutes of Public Health Laboratory Service Board 26 January 1984 pp8-9 PHEN0002505

the healthcare facilities.<sup>1481</sup> The 1967 Public Health Act (Northern Ireland)<sup>1482</sup> mandated that the responsibility for infectious disease control shift from local authorities to county health authorities. Until 1973, public health in Northern Ireland was administered by County Medical Officers across eight health authorities (comprising two urban and six county health bodies), each supported by a County Public Health Inspector and mirrored by district-level officers.<sup>1483</sup>

The establishment of emergency public health laboratories during the war significantly enhanced microbiology services both locally and nationally. In 1953, the Northern Ireland Central Public Health Laboratory was established in Belfast to oversee and coordinate the activities of a network of subsidiary laboratories throughout the region. This central laboratory was crucial for specialised microbiological and epidemiological investigations, supporting a broader regional health infrastructure.<sup>1484</sup>

Northern Ireland’s approach to health service reorganisation involved setting up four health and social services boards. These boards, in direct communication with the Department of Health and Social Security (Northern Ireland), were responsible for both personal social services and health. Similarly to Scotland, there was no separate administration for family practitioner services in Northern Ireland. Instead, the functions typically associated with community health councils were carried out by district committees.<sup>1485</sup>

The Communicable Disease Surveillance Centre (Northern Ireland) (“CDSC(NI)”) was established in 1999 based at Belfast City Hospital under the remit of the CMO for Northern Ireland, to provide an enhanced surveillance function and service for notifiable diseases. Prior to the establishment of CDSC(NI), a senior medical officer within the Department of Health had among their responsibilities a remit for communicable disease.<sup>1486</sup>

## Wales

Ministerial responsibility for the health service in Wales transferred in 1969 to the Secretary of State for Wales and the Welsh Office under the Transfer of Functions (Wales) Order 1969. The reorganisation in Wales closely mirrored that of England, but with a twist. The Welsh Office assumed a dual role, functioning both as a central government department and as a regional health authority. The combination of responsibilities allowed for a more centralised approach to health administration in Wales.<sup>1487</sup>

The PHLS had laboratories in Cardiff, Swansea, Carmarthen and Rhyl, which each investigated microbiological outbreaks in its area. CDSC Cardiff was effectively a Welsh

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1481 Health Services Act (Northern Ireland) 1948, Elder *Health Services of Northern Ireland* British Journal of Preventive and Social Medicine 1953 RLIT0002392

1482 Public Health Act (Northern Ireland) 1967 RLIT0002409

1483 Privilege *Four Decades of Public Health* p4 WITN3449008

1484 Elder *Health Services of Northern Ireland* British Journal of Preventive and Social Medicine 1953 p5 RLIT0002392

1485 Holland and Stewart *Public Health: The vision and the challenge* 1998 p4 RLIT0002250

1486 Written Statement of Aidan Dawson para 4.1a, para 4.2a WITN7561001

1487 Holland and Stewart *Public Health: The vision and the challenge* 1998 p4 RLIT0002250

branch of the national CDSC at Colindale although the PHLS laboratories in Wales fed into the overall picture at Colindale. The CDSC in Wales was headed by a consultant regional epidemiologist with support from a second consultant epidemiologist. The function of the CDSC Wales also included acting as an advisor to the CMO at the Welsh Office on the epidemiology and control of communicable diseases in Wales.<sup>1488</sup>

## Scotland

In Scotland, the NHS had been established by the National Health Service (Scotland) Act 1947. The National Health Service (Scotland) Act 1972 abolished the tripartite structure and led to the establishment of 15 health boards. These boards, which did not include a regional tier of administration, reported directly to the Scottish Office. In this setup, there was no separate administrative structure for family practitioner services. Instead, the Scottish version of community health councils, known as local health councils, were established to oversee these services.<sup>1489</sup>

The situation in Scotland was distinct from that of England, Wales, and Northern Ireland in that during and after the Second World War, public health bacteriology in Scotland was primarily provided by laboratories in four Scottish universities. The PHLS was not expanded to cover Scotland, and the coordination of communicable disease control administration in Scotland developed independently from England, with few formal links between the PHLS and the Scottish laboratories.<sup>1490</sup>

It was not until after a typhoid epidemic in Aberdeen in 1964 that the Communicable Diseases (Scotland) Unit (“CDSU”) was established in 1969. The CDSU performed epidemiological surveillance functions similar to the CDSC in England and Wales, but the laboratories providing data on samples were not managed directly by the CDSU; they remained part of academic institutions, NHS hospitals, and private organisations.<sup>1491</sup>

The information and statistics division of the Common Service Agency also conducted significant epidemiological work and was responsible for commissioning a network of microbiological laboratories. While the Scottish laboratory system was largely self-sufficient, it relied on the PHLS laboratories in England and Wales for certain specialised reference services. In 1989, the Environmental Health (Scotland) Unit was established to provide advice on the epidemiological aspects of environmental health hazards. The CDSU and the Environmental Health (Scotland) Unit were merged in 1993 to create the Scottish Centre for Infections and Environmental Health.<sup>1492</sup>

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1488 Written Statement of Professor Stephen Palmer paras 5.1-6.a.2 WITN7654001

1489 Holland and Stewart *Public Health: The vision and the challenge* 1998 p4 RLIT0002250

1490 Rowland *Mapping Communicable Disease Control Administration in the UK* 2006 p21 RLIT0002277

1491 Rowland *Mapping Communicable Disease Control Administration in the UK* 2006 p21 RLIT0002277

1492 Rowland *Mapping Communicable Disease Control Administration in the UK* 2006 p21 RLIT0002277

## Role in disease surveillance/The role of PHLS and CDSC in surveillance and assessing risk

### Hepatitis in renal units

The PHLS proved critical in responding effectively to outbreaks of hepatitis, particularly in the late 1960s and early 1970s, when Hepatitis B posed a significant threat to renal units in the UK. How did this account of eventual success start?

The PHLS's involvement began with its efforts to manage and control the spread of hepatitis in renal units, beginning with surveillance, in the light of which protective measures could be proposed.

The Working Party on Haemodialysis Units, headed by Dr Brendan Moore, reported in 1968. It outlined major microbiological hazards of dialysis, including hepatitis, and pointed to preventive measures that all renal units could take.<sup>1493</sup> One of the primary measures that was being assessed was the use of immunoglobulin to prevent the spread of hepatitis, although there remained divided opinion over its efficacy.<sup>1494</sup>

The PHLS placed responsibility for each dialysis unit on the hospital bacteriologist, emphasising local decision-making and procedures.<sup>1495</sup> This approach underlined the importance of local management in controlling infection spread, with guidelines and policies set at a higher level to guide these local efforts.

By 1968, the PHLS advocated for the introduction of hepatitis notifications, although distinguishing between Hepatitis A and B was deemed impractical. The growing awareness of the prevalence of hepatitis led to provision for the notification of cases of the disease from June 1968. It was intended that all forms of "infective jaundice" (including "serum" hepatitis) would be covered.<sup>1496</sup> This was 16 years after the World Health Organization's Expert Committee on Hepatitis had recommended that "*both infectious and serum hepatitis should be made compulsorily notifiable in all countries as soon as circumstances permit.*"<sup>1497</sup>

The DHSS convened the Rosenheim Committee in 1970 to advise on hepatitis outbreaks in renal units. The Rosenheim Committee's recommendations in 1972, building upon the PHLS's groundwork, led to nationwide directives on screening and exclusion policies

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1493 PHLS Working Party on Haemodialysis Units *Infectious Risks of Haemodialysis – Some Preventive Aspects* British Medical Journal 24 August 1968 DHSC0003716\_095

1494 Pollock and Reid *Assessment of British Gammaglobulin in Preventing Infectious Hepatitis* British Medical Journal 24 August 1968 RLIT0002247

1495 PHLS Working Party on Haemodialysis Units *Infectious Risks of Haemodialysis – Some Preventive Aspects* British Medical Journal 24 August 1968 p7 DHSC0003716\_095. See for example: Precautions taken to prevent Hepatitis in The London Hospital Dialysis and Transplantation Unit 16 October 1970 DHSC0103090\_155

1496 Public Health (Infective Jaundice) Regulations 1968 SI 1968/861 RLIT0002284. Scotland had required notification of infective jaundice since 1932, though that regulation defined infective jaundice as Weil's disease until amended regulations were put forward: Public Health (Infectious Diseases (Scotland) Amendment Regulations 1968 RLIT0002283

1497 World Health Organization Expert Committee on Hepatitis First Report March 1952 p16 RLIT0000215

for renal units.<sup>1498</sup> The centralised approach, along with continued monitoring, effectively curtailed hepatitis outbreaks in UK renal units.<sup>1499</sup>

The PHLS's response to the outbreaks of hepatitis in renal units was multifaceted, involving the setting up of working parties, emphasising local responsibility, conducting extensive monitoring and surveillance, initiating antigen testing, and collaborating with various local and national bodies. This comprehensive approach, guided by the PHLS's expertise and the Rosenheim Committee's recommendations, was instrumental in controlling and eventually eliminating hepatitis outbreaks in renal units across the UK.

### The response of PHLS and CDSC to AIDS

The surveillance of AIDS in the United Kingdom was carried out by the CDSC in association with the Communicable Diseases (Scotland) Unit, and followed the report of the first case in a British patient in *The Lancet* on 12 December 1981.<sup>1500</sup>

In August 1982, the CDSC set up a surveillance scheme to monitor opportunistic infections and cases of Kaposi's sarcoma, based on death certificates identified by the Office of Population, Censuses, and Surveys ("OPCS"); information on opportunistic infections on laboratory report forms; and information from genitourinary medicine clinics.<sup>1501</sup> Dr Galbraith wrote to venereologists and dermatologists in England and Wales in September 1982 seeking their "*cooperation*" in a trial clinical reporting system of Kaposi's sarcoma due to the "*inadequacies of existing surveillance systems*".<sup>1502</sup>

On 24 March 1983 Dr Galbraith wrote to Dr Charles Rizza of the Oxford Haemophilia Centre regarding the surveillance of AIDS and Kaposi's sarcoma. Dr Galbraith stated that the CDSC had received reports of cases of Kaposi's sarcoma and opportunistic infections in homosexuals: "*We should be very interested to hear of any cases of A.I.D.S., occurring in haemophiliacs in England and Wales and would greatly value your advice and help on how we might discover these. We would also appreciate any information you can provide about the distribution and use in England and Wales of imported factor VIII concentrate from the United States of America.*"<sup>1503</sup>

1498 Advisory Group on Hepatitis and the Treatment of Chronic Renal Failure *Hepatitis and the Treatment of Chronic Renal Failure: Report of the Advisory Group 1970-1972* March 1972 LOTH0000111\_013

1499 PHLS *Decrease in the Incidence of Hepatitis in Dialysis Units associated with Prevention Programme* British Medical Journal 28 December 1974 RLIT0002248, PHLS *Hepatitis B in retreat from dialysis units in United Kingdom in 1973* British Medical Journal 26 June 1976 RLIT0002275

1500 Du Bois et al *Letter to the Editor on Primary Pneumocystis Carinii and Cytomegalovirus Infections* The Lancet 12 December 1981 p2 PRSE0004476

1501 CDSC *The Surveillance of Kaposi's Sarcoma and Opportunistic Infections in Homosexual Males in England and Wales* Communicable Disease Report 27 August 1982 pp3-4 RLIT0002181

1502 Draft Letter from Dr Galbraith September 1982 HSSG0010056\_037

1503 Letters between Dr Rizza and Dr Galbraith March 1983 p1 HCDO0000392\_084



In his response to Dr Galbraith on 28 March 1983, Dr Rizza communicated his awareness of the CDSC’s surveillance scheme from discussions with Dr John Craske and that “we shall do all we can to help you with your surveillance.”<sup>1504</sup>

In April 1983 a letter from Dr Brendan O’Connor, Dr Marian McEvoy and Dr Galbraith, from CDSC, was published in *The British Medical Journal*, noting the three existing sources of information (OPCS data, laboratory reports and clinical reports from dermatologists and venereologists), and recording that: “Because patients may present to doctors in other specialities, however, we think that our data underestimate the size of the problem.” All doctors were asked to let CDSC know when a patient with AIDS or Kaposi’s sarcoma came under their care.<sup>1505</sup> A similar request was made in a letter published in *The Lancet*.<sup>1506</sup> This message was also disseminated in the wider press.<sup>1507</sup>

Dr Mary Sibellas, of Med IMCD, drew the attention of Dr Ian Field to this article on 26 April 1983, noting that “CDSC are monitoring the situation closely and are keeping us informed.”<sup>1508</sup>

In May 1983, Professor Arthur Bloom reported a probable case of AIDS to CDSC. Dr Galbraith in turn reported to Dr Sibellas on 6 May 1983 information about a patient in Cardiff with haemophilia with “the right symptoms and signs for a diagnosis of AIDS” and spoke of three cases in Spain of people with haemophilia thought to have AIDS.<sup>1509</sup>

The initial findings of the CDSC surveillance scheme were published in *The British Medical Journal* on 6 August 1983. The article detailed the cases reported between September 1982 and the end of July 1983 and included retrospective data from 1 January 1982 onwards. By this time, 14 patients had been reported to the CDSC and confirmed as having AIDS with 5 of the patients having died. 1 of the 14 patients was confirmed as having haemophilia and receiving US-imported Factor 8 concentrates.<sup>1510</sup> Since the Inquiry knows that there had been at least two cases of AIDS by this time,<sup>1511</sup> one of which it seems had not yet been notified to CDSC, it seems that Drs O’Connor, McEvoy and Galbraith’s view that their data underestimated the size of the problem was fully justified. Indeed, on learning about one case only after the patient had died, Dr Galbraith expressed his disquiet to the UK Haemophilia Centre Directors’ Organisation (“UKHCDO”).<sup>1512</sup>

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1504 Letters between Dr Rizza and Dr Galbraith March 1983 p2 HCDO0000392\_084

1505 O’Connor et al *Letter to the Editor on Acquired immune deficiency syndrome* British Medical Journal 23 April 1983 HSSG0010056\_038

1506 O’Connor et al *Letter to the Editor on Kaposi’s Sarcoma/AIDS Surveillance in the UK* The Lancet 16 April 1983 MACK0000587\_002

1507 The Times *Doctors asked to report Aids cases* 23 April 1983 DHSC0002225\_033

1508 Memo from Dr Sibellas to Dr Field 26 April 1983 DHSC0003824\_182

1509 Memo from Dr Sibellas to Dr Ronald Oliver 6 May 1983 DHSC0002227\_021

1510 CDSC *Surveillance of the acquired immune deficiency syndrome in the United Kingdom, January 1982-July 1983* British Medical Journal 6 August 1983 p2 DHSC0002231\_019

1511 One in Cardiff, one in Bristol. In addition, at least one boy at Treloar’s was showing the stigmata of AIDS at this stage. See the chapter on *Knowledge of the Risks of AIDS*.

1512 Draft Minutes of Haemophilia Reference Centre Directors meeting 19 September 1983 p4 PRSE0003196

Differing views were expressed at the meeting of UKHCDO reference centre directors on 19 September 1983 about notifying the CDSC about suspected AIDS patients. Professor Bloom felt that it was the responsibility of the haemophilia centre directors to report directly to CDSC as well as to Dr Craske. Some felt that the CDSC should be informed directly whereas others were concerned that the notification of suspected cases might result in unnecessary publicity and possibly even identification of patients by the press. Dr Diana Walford said that the DHSS relied on the CDSC for confirmation of cases. It was agreed by a majority that reporting to CDSC should be through Dr Craske, after discussion with the director involved in the patient's management.<sup>1513</sup>

As yet, arrangements for notification to the blood services with a view to identifying risk and tracing potentially infected donors and, in turn, tracing the recipients of any potentially infected donation which came from such a donor, had not been finalised. That happened in 1984, when Dr Galbraith and Dr McEvoy, both of CDSC, met Dr Harold Gunson to discuss the process. It was settled that the CDSC would inform the appropriate regional transfusion director when a patient was found to be infected with HIV or diagnosed with AIDS. Any blood donations would be traced for the previous five years, and if plasma had been sent to the Blood Products Laboratory for fractionation, Dr Richard Lane was to be informed as soon as possible.<sup>1514</sup>

## Commentary

It will have come as a surprise to many readers that Sir Liam Donaldson, as CMO, spoke of there having been at least 30 previously unknown infectious diseases which had become prominent in the 30 years between 1970 and 2000.<sup>1515</sup> Similarly, it will come as a surprise to many to learn that a similar number of attempted terrorist attacks is being disrupted on average every four years by the national security agencies in the UK. No one could or would dispute the need in the latter case for constant surveillance, analysis, and action. No one could dispute the need for local knowledge and action, centrally coordinated, and its proper funding.

Yet it is a paradox of public health that the more speedy and effective reporting, surveillance, analysis and response are in respect of communicable disease, the less visible the results are to the public who are protected. And because they are less visible the public health effort seems less important, less demanding of time and effort, and – critically – funding and the maintenance of an effective system. There is wide agreement in the evidence to the Inquiry that public health protections reduced significantly after 1974, as a consequence of the mindset that led to the changes made in the health service reorganisation of that year – that the threat posed by infectious disease had largely been overcome; that the emphasis

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1513 Draft Minutes of Haemophilia Reference Centre Directors meeting 19 September 1983 p4 PRSE0003196

1514 Note on surveillance of AIDS in relation to blood transfusion meeting 4 April 1984 CBLA0001833. See the chapter on *HIV Lookback*.

1515 Department of Health *Getting Ahead of the Curve: A strategy for combating infectious diseases (including other aspects of health protection)* 10 January 2002 p10 DHSC5017529

now should be on protection by promoting lifestyle changes (health promotion), rather than the less individual dangers of communicable disease (health protection); that the need for expert medical epidemiology at a local level had lessened and would diminish further.

A consequence was as the Expert Group on Public Health and Administration have identified in their report to the Inquiry:

*“Public health services in the UK have been the target of several major reorganisations in the last 50 years, which have been associated with budgetary cuts, closures, and loss of staff and expertise. The sheer number and scale of reorganisations has inevitably been extremely disruptive, firstly weakening, and then removing, communicable disease control at local level and, from 1990, increasing marketisation and outsourcing. The overall effect has been to make public health services more fragmented and less cohesive, reducing the number of specialists, particularly those with medical training, and also reducing the overall expertise of the workforce.”*<sup>1516</sup>

A system which had been largely effective, and admired internationally, in which the MOH of a local authority had a central role to play in protection against the spread of infectious disease was partly dismantled when the post of MOH was abolished in 1974.

A number of respected commentators reflect similar views about the weakened nature of the public health response to infectious disease after 1974, and have given broadly similar views about what might be required to put this right.

Thus, in 1981 Dr Galbraith (of the CDSC) identified a need for there to be a clinical epidemiologist in each district, alongside the district medical officer, and thought that the resulting local epidemiology units should be linked through regionally located specialist epidemiologists to a national specialist unit, thus providing a degree of coordination between local identification and control of disease and the national centre that had been lacking.<sup>1517</sup>

In 1982, the chairman of the PHLS Board observed that:

*“As there are now so few Medical Officers (Environmental Health) with substantial experience of communicable disease control in post, active intervention by PHLS laboratories is playing an increasing part in the investigation and control of infectious disease incidents and such intervention in several places simultaneously requires co-ordination ... As the incidence of infectious diseases decline, not only does knowledge and competence to diagnose and control them, but the need for vigilance increases as herd immunity diminishes.”*<sup>1518</sup>

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1516 Expert Report to the Infected Blood Inquiry: Public Health and Administration August 2022 p14 EXPG0000048

1517 Galbraith *A national public health service* Journal of the Royal Society of Medicine January 1981 pp2-6 RLIT0001747

1518 *Review of the functions and organisation of activities of the Public Health Laboratory Service* 28 October 1982 as quoted in: Supplementary Expert Report to the Infected Blood Inquiry:

By 1986, an inquiry was called for. The Acheson Report identified the adverse effects of the 1974 changes on public health protection, complaining of its effect on the morale of community physicians, the reduction in the number of posts, and uncertainty about the number and nature of future jobs. The evidence put to the Committee of Inquiry suggested that this continued uncertainty was likely to mean that fewer able doctors would in future enter the specialty. As a result, health authorities, local authorities and the public could lose access to appropriate public health advice. The Acheson Report recommended an increase in the number of consultants in public health medicine.<sup>1519</sup>

Despite these ambitions (the Acheson Report recommended a 16% expansion from 649 to 750 public health physician consultants over the 10 years to 1998, and sought to emphasise the importance of medical expertise) the numbers in post had dropped to 405 (less than half the number per million of the population which the Acheson Report had recommended) by 2021, and in the period from 2014 to 2021 the numbers of public health consultants declined by 17%, and the number of non-clinical public health specialists increased by 39%.<sup>1520</sup>

The same theme of unease at the readiness of the system nationally to face serious threats of infectious disease was repeated in Sir Liam Donaldson's 2002 report.<sup>1521</sup>

In short, it is impossible to avoid the conclusion that the control of communicable disease by public health measures was given less value in the years 1970 to 2000 than it had been given earlier; and that the warning voices that had been raised suggesting improvements to the system did not reach ears as willing to listen as they would have been in the 1940s and 1950s when the systems in operation to control communicable disease worked well.

In a report supplementary to that of the Public Health and Administration Expert Group, Professor Allyson Pollock and Dr James Lancaster expressed the conclusion that:

*“Notwithstanding public expenditure constraints throughout the 1970s and 1980s there was a strong system and network developing that linked the local and the national. However, the opportunities to establish a regional network of epidemiologists to link the newly formed CDSC in 1977 and from 1974, the proper officers in local authorities, and to complement and supplement the activities of the PHLS network of national and peripheral PHLS laboratories, were not grasped until the early 1990s. This meant that CDSC, with a small number of staff undertaking a wide range of roles and dealing with many different outbreaks*

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Structures and Funding of the Communicable Disease Control System in England 15 November 2022 p7 EXPG0000129

1519 Public Health in England: The Report of the Committee of Inquiry Into the Future Development of the Public Health Function January 1988 p42 RLIT0001743

1520 Expert Report to the Infected Blood Inquiry: Public Health and Administration August 2022 p17 EXPG0000048, Public Health in England: The Report of the Committee of Inquiry Into the Future Development of the Public Health Function January 1988 pp42-43 RLIT0001743. The number of public health specialists have increased from 2012 when there were around 1,100 working in England to 1,227 full-time equivalent posts in 2021-2, but the proportion of consultants has, as the text states, dropped by nearly a fifth.

1521 Department of Health *Getting Ahead of the Curve: A strategy for combating infectious diseases (including other aspects of health protection)* 10 January 2002 p10 DHSC5017529

*and investigations, could only act in an advisory capacity and had insufficient capacity to provide regional support.*

*If regional epidemiologists had been appointed and had sat on committees with regional haematologists and on local joint consultative committees with clinicians and MOEHs, it is plausible that the risks from infected blood following Galbraith's crucial letter in May 1983 warning about the risks of HIV from infected blood would have been more widely communicated and understood by clinicians."*<sup>1522</sup>

This is tentatively expressed. If public health expertise (in the control of communicable disease and epidemiology) is given a high value then people who might be influenced by it – in particular clinicians and administrators – will give it more weight than if that expertise is given a lower standing. One of the questions which has arisen in this Inquiry is why it was that Dr Galbraith's letter of 9 May 1983 did not find its way before politicians, decision-makers, and senior civil servants as, regularly, witnesses from their different perspectives have accepted in testimony that it should. An answer may be that the letter came during what Professor Armstrong called "*the epidemiological transition*".<sup>1523</sup> This mindset, coupled with a culture in which generally it had been thought that infectious disease had been mastered, and in which the control of communicable disease had been made visibly less important by the 1974 changes, probably contributed to that letter being ignored or passed over when it should not have been, rather than taken more seriously.

Some of the concepts which were familiar to epidemiologists (such as the difference between risk and incidence; the significance of incubation periods; the exponential curve of many epidemics; the importance of speed and decisiveness in reacting to control the spread of disease; and the knowledge that what is in a foreign country may very easily be a foretaste of what may happen in the UK) were not appreciated as they should have been. Had they been, many fewer infections would have occurred. A weakness of epidemiological input, across medicine, thus contributed to the suffering of many. This cannot, however, necessarily be laid at the door of the way in which the UK public health systems were organised in the 1970s and 1980s.

Professor Pollock and Dr Lancaster were right to be tentative in what they wrote. There is insufficient evidence to say what immediate practical difference it would have made if public health had been given an appropriate, higher, value. However, both these last observations and the evidence the Inquiry has heard emphasise the importance that needs to be placed on public health, and the need to strengthen it: it will almost certainly have to meet the threat of further as yet unknown viral or other biological threats, and needs to be valued generally by society if it is to do so. We may need to remember that where it succeeds, we see simply the absence of infection. But the absence of infection should not lead to calls for any absence of a well-resourced system of protection.

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1522 Supplementary Expert Report to the Infected Blood Inquiry: Structures and Funding of the Communicable Disease Control System in England 15 November 2022 p14 EXPG0000129

1523 (Professor David Armstrong) Public Health and Administration Expert Group Transcript 3 October 2022 p85 INQY1000251



## 5.9 vCJD

This chapter describes vCJD and assesses the government response to the risks of its transmission by blood or blood products. It explores the contrast between the response to HIV in the 1980s and the response to vCJD in the 1990s/2000s.

### Key dates

**September 1985** first confirmed BSE case in cows.

**March 1996** vCJD formally identified in humans; probable link between BSE and vCJD announced in Parliament.

**August 1996** blood transfusion services required to ask about family history of CJD.

**October 1997** CMO's statement reporting that there are patients with vCJD who had been blood donors; MSBT decides that recipients of possibly infected transfusions do not need to be told; NBA recalls batches of Factor 8 and albumin after a donor develops vCJD.

**November 1997** the Government decides on leucodepletion; UKHCDO recommends recombinant Factor 8 for all with Haemophilia A.

**July 1998** leucodepletion programme is implemented.

**November 1998** Government decides that blood products will no longer be made from UK plasma.

**August 2000** CMOs set up the CJD Incidents Panel.

**October 2000** BSE Inquiry report published and compensation is announced.

**December 2002** the Government purchases US plasma collector.

**December 2003** death of a patient thought to have been infected with vCJD through transfusion is announced. People who received transfusions from donors who subsequently developed vCJD are notified.

**March 2004** exclusion of donors who had received blood transfusions after 1 January 1980.

**July 2004** second case of transfusion-related vCJD is reported.

**September 2004** haemophilia centres notify people who received factor products between 1980 and 2001.

### People

**Professor John Collinge** head of the Medical Research Council Prion Unit, University College London Institute of Neurology

**Dr Patricia Hewitt** Standing Advisory Committee on Transfusion Transmitted Infections

**Professor James Ironside** professor, clinical neuropathology

**Dr Robert Will** professor, clinical neurology

### Abbreviations

**CJDIP** CJD Incidents Panel

**MSBT** Microbiological Safety of Blood and Tissue

**NCJDRSU** National Creutzfeldt-Jakob Disease Research & Surveillance Unit

**TMER** Transfusion Medicine Epidemiology Review

## Introduction

The central nervous system – brain and spinal cord – may degenerate over time. Neurodegenerative disorders may display themselves as losses of cognitive function, or motor capabilities, or both.

A variety of different causes may be responsible for this. Amongst them is a form of disease first identified by two neurologists – Hans Creutzfeldt and Alfons Maria Jakob – which thus became known as Creutzfeldt-Jakob Disease (“CJD”). This is a prion disease. Prion diseases form a group of degenerative brain diseases. They are always progressive and invariably fatal.

Prions are proteins. Many prion proteins sit on the surface of brain cells. This is normal. Such proteins are three dimensional in shape, and this 3D shape is essential for their function. Prion disease occurs when the protein does not fold into its normal shape but misfolds. It can do so in a way such that many individual prion protein molecules stick together, forming long chains or assemblies of protein. These form fibres of protein (technically referred to as amyloid). As the amyloid fibres grow, by recruiting more of the normal protein into the disease-associated form, they also fragment: and as they fragment they effectively produce more amyloid. Professor John Collinge described it as if there were “*seeds in the brain ... which in [sic] then in turn grow ... fragment and form more seeds.*”<sup>1524</sup> It is thus a self-propagating process.

And prion protein is not a virus: it has no DNA or RNA of its own. It is purely protein. Chemically, therefore, a misfolded protein is indistinguishable from a correctly folded protein. This creates particular challenges in distinguishing a diseased prion from a healthy prion protein. It also means that the immune system does not respond to the threat posed by the diseased prion. A normal defensive immune response begins with the recognition of a virus, other antigen, or protein as being “foreign”.<sup>1525</sup> Thus the body of a person who is infected with abnormal prion does nothing of itself which slows the inevitable progress of replication of the misfolded proteins, the development of amyloid, and the onset of symptoms.

These prions, which cause disease, arise in one of three forms (though the third has two subsets). The first, and commonest, is as a sporadic disease (sporadic CJD: “sCJD”). This occurs at random and it is similar in this respect to contracting cancer but is much more rare. About 1 in 5,000 people will develop this during their lifetime,<sup>1526</sup> compared to 1 in 2 people developing some form of cancer.

Second, there are inherited forms: a genetic mutation of the prion protein gene, inherited from a parent, results in spontaneous mutation at some stage during adult life. The disease

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1524 Professor John Collinge Transcript 13 May 2022 pp21-23 INQY1000206

1525 See chapter *Blood and Transfusion* for a fuller explanation.

1526 Professor John Collinge Transcript 13 May 2022 p23 INQY1000206

then progresses in the same way as sCJD. Inherited disease accounts for about 15% of UK patients.<sup>1527</sup>

Third are the forms of disease that are acquired as a result of some exposure. There are two subsets, depending on the routes of exposure. The first subset consists of medical accidents. Examples include the use of contaminated neurosurgical instruments for certain tissue grafts, or the use of particular hormones to treat growth deficiency (some batches of hormones derived from pituitary glands were contaminated with CJD prions because they were extracted from human tissues which had been pooled together). The second subset of acquired CJD is variant CJD (“vCJD”). This is usually due to dietary exposure to bovine spongiform encephalopathy (“BSE”) prions.<sup>1528</sup> However, there have to date been five known cases where vCJD has spread from one infected person to another through the transfusion of blood or blood products.<sup>1529</sup>

The protein strains which cause classical CJD (the sporadic or inherited types) propagate almost exclusively in the brain and spinal cord. In vCJD, however, the development of diseased prions involves the lymphoreticular system. Thus it is thought that lymphoreticular tissues – such as the tonsils, and patches of lymphoid tissue in the gut – are likely to be the first places to be infected. A likely model is that prions then spread along the nerves in the lymphoid tissue, until they reach the spinal cord and then go up into the cranial nerves. Eventually, they get to the brain itself and begin to cause the neurological disease recognised clinically as vCJD. The whole lymphoreticular system is involved: spleen, lymph nodes around the body, tonsils, and gut-associated lymphoid tissue.<sup>1530</sup>

## Developing knowledge of vCJD and reaction to it

BSE, or “mad cow disease” as it became known, was first confirmed in September 1985 at a farm in Sussex. Further cases followed, rapidly rising in number. There was a risk that it might jump the species barrier and infect humans through their eating of beef or beef derivatives.<sup>1531</sup> Such was the risk that by 1989 high-risk food stuffs such as offal were banned for human consumption, and many British consumers stopped buying beef because of their fears of what it might contain.

By April 1990, as the epidemic spread rapidly, a Spongiform Encephalopathy Advisory Committee (“SEAC”) was set up to advise the Department of Agriculture, Fisheries and Food and the Department of Health, and the National Creutzfeldt-Jakob Disease Research and Surveillance Unit (“NCJDSU”, later “NCJDRSU”) was set up to monitor cases of CJD in

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1527 Professor John Collinge Transcript 13 May 2022 p24 INQY1000206

1528 Professor John Collinge Transcript 13 May 2022 p24-25 INQY1000206

1529 Expert Report to the Infected Blood Inquiry: Statistics September 2022 pp95-98 EXPG0000049

1530 Professor John Collinge Transcript 13 May 2022 pp27-28 INQY1000206

1531 Professor Collinge referred to Kuru, an acquired prion disease historically seen in a small area of the Highlands Region of Papua New Guinea. At mortuary feasts it was the practice in that area for the deceased to be consumed and this led to an epidemic of prion disease. Professor John Collinge Transcript 13 May 2022 pp25-26 INQY1000206

the UK in order to identify any changes in the pattern of disease that might be attributable to the emergence of BSE.

The epidemic amongst cattle spread rapidly, reaching its height in 1992. A yet more worrying development was reported by Dr Robert Will and Dr James Ironside<sup>1532</sup> on 8 March 1996 when the same disease as BSE was first formally identified as vCJD in humans. It had crossed from cows to people, and was labelled new variant CJD (“nvCJD”) because of its similarities to classical CJD, before being known simply as vCJD.<sup>1533</sup>

Twelve days after Drs Will and Ironside had presented their work (to SEAC), the Secretary of State for Health, Stephen Dorrell, announced in Parliament that there was a probable link between BSE in cows and the new variant (now known as vCJD) in humans.<sup>1534</sup> This ministerial announcement was followed by a publication in *The Lancet* of the findings of Dr Will and Dr Ironside. The features were that sufferers tended to have a young age at onset, a long duration of illness, an absence of mutations in the prion protein gene (the PrP gene), and developed characteristic plaques involving extensive prion deposition throughout the brain which had not previously been seen in CJD.<sup>1535</sup> This made for a clear distinction between classical CJD and vCJD.

vCJD seemed similar to BSE in cattle. In a similar disease (“scrapie”) in sheep to BSE in cattle the prions could be detected in the sheep’s tonsils. Could it, then, be found in human tonsils? In late 1996 the National Prion Clinic which had been set up under Dr Collinge checked to see. They discovered that it could quite easily be found. This realisation had implications: since prions could be detected quite readily in tonsils, lymph nodes and the spleen from patients who had died from vCJD, they did so in places where cells of the immune system, such as white blood cells, circulate freely. White blood cells, as the name suggests, also circulate in the bloodstream. This implied that the abnormal prions of vCJD might not only be transmissible by eating BSE-infected meat, but also through the blood circulation. It also implied that there was a general risk that surgical instruments might be contaminated, not only where surgery was being done on the brain, but also more generally in other body tissues where the abnormal prions might be present in lesser numbers, since prions stick “*rather avidly to surgical stainless steel.*”<sup>1536</sup>

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1532 Subsequently both professors.

1533 Minutes of Spongiform Encephalopathy Advisory Committee meeting 8 March 1996 pp5-8 DHSC0004445\_043. The first death from vCJD was found to have occurred on 21 May 1995, when 19-year-old Stephen Churchill died – although the UK Government continued to emphasise the safety of British beef and, in October 1995, concluded that there was “*currently no scientific evidence*” to link BSE and vCJD. The Chief Medical Officer (“CMO”) quoted in a Department of Health press release: Department of Health Press Release *CJD Deaths in Line with Levels Worldwide* 5 October 1995 p2 CABO0000292\_013

1534 Department of Health Press Release *CJD and Public Health: Stephen Dorrell Statement* 20 March 1996 CABO0000383\_036

1535 Will et al *A new variant of Creutzfeldt-Jakob disease in the UK* *The Lancet* 6 April 1996 p2 HSOC0010099. Dr Will and Dr Ironside both worked for the NCJDSU.

1536 The words are those of Professor Collinge. Professor John Collinge Transcript 13 May 2022 pp30-32 INQY1000206

The worrying features of *The Lancet* publication were such that only three days later an ad hoc meeting was organised at the Royal College of Physicians of Edinburgh to discuss its implications for the blood transfusion services in the UK. Dr Ironside made a presentation. There was little information as to whether BSE/vCJD **could** be transmitted by the transfusion of blood and blood products. However, this **could not** be excluded. Nor could it be assumed that it would behave in a manner similar to that of classical CJD. The meeting noted a need to consider what plasma fractionators should do, and that because the level of BSE in the UK was significantly higher than in other countries “*it may thus be appropriate to be proactive in this area.*”<sup>1537</sup>

Proactive protective responses were also agreed. The transfusion services were to take urgent action to start direct questioning of blood donors. It was also thought essential to identify whether patients who had been identified as having had CJD had ever donated blood. It was agreed recommendations should be developed to consider what action should be taken where a new case of CJD was identified in a current or former donor. The feasibility of a form of “lookback” to assist in identifying the transmissibility of vCJD by blood needed to be assessed since it was recognised that it was necessary to investigate systematically whether reported cases of vCJD had themselves received transfusions of blood or blood products prior to the symptoms of the disease. Possible quarantining of donations of frozen blood components was considered.<sup>1538</sup>

Thus, from 1 August 1996 blood transfusion services throughout the UK were required to ask all blood donors whether they had a family history of CJD. Where a close family member with CJD was a direct bloodline relative (eg parent, brother, child) the potential donor was to be advised not to give blood.<sup>1539</sup>

By June 1997, SEAC reported that the evidence favoured a conclusion that there was indeed a link between BSE and vCJD, but this was not (yet) sufficient to be regarded as scientific proof of a causative link.<sup>1540</sup>

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1537 It was organised by Dr Angela Robinson (National Blood Authority) and Professor John Cash (Scottish National Blood Transfusion Service) and 16 of the major figures in blood transfusion in the UK were present. Notes of Royal College of Physicians of Edinburgh meeting 9 April 1996 p3 NHBT0115407

1538 Notes of Royal College of Physicians of Edinburgh meeting 9 April 1996 pp1-3 NHBT0115407

1539 National Blood Service *Creutzfeldt-Jakob Disease: Information for Blood Donors* August 1996 JPAC0000177\_008. From 1 April 1998 donors who had had brain surgery before August 1992 were permanently deferred. Corneal transplants, an operation for a tumour or cyst on the spine before August 1992, or an injection of human pituitary extract such as growth hormones before 1987 were also grounds for deferral. (Growth hormones derived from pituitary glands were a source of acquired CJD). UKBTS/NIBSC Medical Assessment of Donors April 1998 p17, pp22-23, p33, p93 JPAC0000160\_002

1540 Letter from the Department of Health to the Prime Minister 30 March 1997 CABO0000009\_002, Department of Health *Research Into Link Between New Variant CJD and BSE: Publication of Latest Scientific Advice* 1 July 1997 DHSC0006880\_072, Minutes of Spongiform Encephalopathy Advisory Committee meeting 23 May 1997 p13 NCRU0000248\_058. The statement was prompted by a letter from the parents of Stephen Churchill, the first person to die of vCJD, asking for SEAC’s considered view on whether there was a causal link. Minutes of Spongiform Encephalopathy Advisory Committee meeting 15 April 1997 pp11-12 DHSC0046994\_003



By 16 September 1997, however, SEAC considered the results of two studies in *Nature* (in advance of their publication at the start of October 1997) and became convinced that the evidence of the link between BSE and vCJD had become “*compelling*”.<sup>1541</sup> Although the primary candidate for transmitting the disease was eating infected beef, it was theoretically possible that it might be transmitted between humans through blood. SEAC thus recommended in their next meeting that the National Blood Authority should take steps towards the leucodepletion of blood (the removal of as many white blood cells as possible from a donation by the available technology) as far as practicable pending the results of an assessment of the risk of transmitting vCJD by this means.<sup>1542</sup>

The Chief Medical Officer (“CMO”) issued a statement on 6 October 1997, which reported that three patients who had suffered from vCJD had been blood donors, and a fourth was suspected of having been one too. The statement noted that “*there is no epidemiological evidence to suggest that classic CJD has been transmitted between humans through blood transfusions or the use of blood products. However we do not know whether the same will apply to nvCJD.*”<sup>1543</sup> Since the Blood Products Laboratory (“BPL”) manufactured blood products from donated plasma it was notified of these three donors. It was ascertained that between them they had provided seven donations of plasma, six of which had been included in fractionation pools for the production of blood products.<sup>1544</sup>

Recipients of the products made from pools containing this plasma had not been notified.<sup>1545</sup> A debate began about whether recipients should be told of the risks they now faced.

In successive days a working party of the Committee on Proprietary Medicinal Products, a European Union body to which the UK had recommended a policy of recall if a plasma pool was found to have been made in part from a donation from someone who had subsequently developed vCJD, agreed that there should be such a recall and SEAC agreed that the surveillance unit would set up a procedure to report cases.<sup>1546</sup>

This in turn was swiftly followed by a meeting of the Advisory Committee on the Microbiological Safety of Blood and Tissue (“MSBT”). This recommended that when the blood services were informed of suspected cases of vCJD confirmed as such by the NCJDSU the recipients of any donation from those people would have to be traced – a process which might seem similar to a “lookback”, save that it was forward-looking: it was not seeking to ask how

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1541 Minutes of Spongiform Encephalopathy Advisory Committee meeting 16 September 1997 pp6-8 WITN3430070, Bruce et al *Transmissions to mice indicate that ‘new variant’ CJD is caused by the BSE agent* Nature 2 October 1997 DHSC0004125\_011, Hill et al *The same prion strain causes vCJD and BSE* Nature 2 October 1997 DHNI0000041\_123. The word “*compelling*” was used in SEAC’s description in its first annual report. First Annual Report of the Spongiform Encephalopathy Advisory Committee 1997-1998 p9 MHRA0020531

1542 Minutes of Spongiform Encephalopathy Advisory Group meeting 24 October 1997 pp7-12 NCRU0000174\_001

1543 Department of Health *CMO Statement on CJD* 6 October 1997 p2 DHSC0041442\_171

1544 vCJD, Blood Components and Plasma Products 30 January 2001 p13 NHBT0001722

1545 vCJD, Blood Components and Plasma Products 30 January 2001 p14 NHBT0001722

1546 Memo from Dr Jefferys to Dr Jones, Mr Kenny and Miss Casemore 23 October 1997 p1 DHSC0041442\_050, Minutes of Spongiform Encephalopathy Advisory Group meeting 24 October 1997 pp11-12 NCRU0000174\_001

the suspected case came to be infected, by tracing back, but who they themselves had infected. It was agreed that it was important still to continue the (retrospectively focused) vCJD lookback.<sup>1547</sup>

The minutes of this MSBT meeting also record a debate about whether to inform recipients that they had been given a transfusion which increased the risks that they would suffer vCJD. The Committee on Proprietary Medicinal Products had advised that those who received **blood products** made from pooled plasma should be told. Should recipients of **single-unit donations of blood** also be told? A Regional Ethics Committee<sup>1548</sup> considering whether to give ethical clearance for a proposed epidemiological review to examine a potential link between transfusion and infection with vCJD had previously advised against telling recipients that they had received a donation which might be infected. It was reported to the MSBT at this meeting that this Committee had been asked to review that decision in the light of the developments described above, but was understood to have upheld the existing line. The chairman of the MSBT “*recognised an apparent inconsistency in following the CPMP [Committee on Proprietary Medicinal Products] advice on blood products but not telling patients, once traced, when labile components [ie blood] had been given to them.*” The decisive reason for keeping quiet, at least so far as the chair was concerned, was “*whether we could do anything about a situation*”. Blood already transfused could not be recalled, but **products** in stock could be, on a precautionary basis.<sup>1549</sup> Disagreement about whether people should be told that they were at risk continued for the next seven years, and is described more fully later in this chapter.

As to recall, there was no such debate. It was swiftly put in place. On 30 October 1997 the National Blood Authority issued a press statement to the effect that it had recalled albumin and Factor 8 from 26 sites within England on the basis that a blood donor who had developed vCJD had contributed to that batch.<sup>1550</sup>

In early November 1997, the Secretary of State for Health, Frank Dobson invited Dr Collinge to meet him in person to advise him about the risks of transmission of vCJD by blood and blood products. The meeting was attended by a number of senior civil servants, the CMO, and the chair of SEAC. Dr Collinge set out how he considered that on the basis of the evidence available at the time much of the infectivity in vCJD was likely to be white-cell-associated. He described the (still) theoretical risk that vCJD might be transmitted

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1547 Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting 27 October 1997 pp3-8 SBTS0000522

1548 Lothian Research Ethics Committee – concerned with Scotland, in particular the Edinburgh area, and the body to which the NCJDSU, which was based in Edinburgh, had to apply to obtain ethical clearance for proposed research. Approval was given by the Committee for a retrospective study to examine a possible link between CJD and blood transfusion (known as the “TMER study” – Transfusion Medicine Epidemiology Review), on the condition that anyone who was traced as a result of the TMER study would not be told of their exposure. Chronology on Precautions on Blood Protection: Transfusion Medicine Epidemiology Review (TMER) 10 January 2005 DHSC0038559\_029

1549 Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting 27 October 1997 p6, p8 SBTS0000522

1550 National Blood Authority Press Release *National Blood Authority Issues Recall Notice on Plasma Products* 30 October 1997 NHBT0005408\_004

through blood and blood products. Technology was available to filter out white cells from blood before it had been transfused (a number of countries already did this, at least to an extent, for reasons unrelated to vCJD, because it may also reduce the transmission of some viruses and unwanted immunological reactions as well as increasing the shelf-life of blood). After questioning Dr Collinge the Secretary of State decided that leucodepletion should take place before either transfusion, or the manufacture of blood products from the blood donated. The Secretary of State took the issue immediately to the Prime Minister (Tony Blair) who agreed straight off, and a decision was taken that day to set the wheels in motion for this.<sup>1551</sup> In a press statement the Government said it had accepted the advice of SEAC to extend the use of leucodepleted blood and blood products as far as practicable, had commissioned an assessment of the risks of human-to-human transmission of nvCJD through blood and blood products, and instructed the National Blood Authority to start work towards the “*possible extension of leucodepletion of blood in order that they are prepared in the event that the risk assessment indicates that this would be a sensible precautionary measure.*”<sup>1552</sup> As it happens, no case of transmission from leucodepleted blood or plasma has ever been recorded.

A further risk reduction measure was advocated by the United Kingdom Haemophilia Centre Doctors’ Organisation (“UKHCDO”), also in November 1997. It issued a press release recommending the use of recombinant Factor 8 for all. Where this was not available, it suggested that the risk of transmission of vCJD would be reduced by using concentrates prepared from using donor plasma collected in countries other than the UK where there were no recorded cases of either vCJD or BSE (eg the US).<sup>1553</sup> The following year, the Department of Health made recombinant available to all children under 16 and new patients in England, matching what was already provided in Scotland, Wales and Northern Ireland, though Scotland and Wales went further.<sup>1554</sup> In Scotland, the Scottish Office made sufficient funding available not only for children but also some adults.<sup>1555</sup> In Wales, recombinant was made available for all patients from 1997.<sup>1556</sup> Adults were increasingly funded through 1998 in Scotland and Northern Ireland.<sup>1557</sup> However, it was not until the 2004/2005 financial year that all patients with Haemophilia A in the UK had access to recombinant Factor 8.<sup>1558</sup>

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1551 Professor John Collinge Transcript 13 May 2022 pp16-17, pp62-63, pp65-66 INQY1000206

1552 Department of Health Press Release *SEAC Advice on Safety of Blood and Blood Products Accepted* 6 November 1997 p1 BART0002084\_002

1553 Letter from Dr Christopher Ludlam to colleagues 25 November 1997 p3 HSOC0015139

1554 Department of Health Press Release *Further Precautionary Measures on Blood Products Announced* 26 February 1998 HSOC0015101\_002, Haemophilia Society Press Release *Haemophilia Society Wins Battle for Recombinant Factor VIII* 26 February 1998 p2 HSOC0016980

1555 Memo from I Snedden of NHS Management Executive to PS/Minister of State 3 June 1996 SCGV0000116\_166, House of Commons written answer on use of synthetic factor VIII for the treatment of haemophilia 10 July 1996 SCGV0000116\_149

1556 Written Statement of Dr Saad Al-Ismael para 46 WITN3761005

1557 Haemophilia Society Press Release *Haemophilia Society Wins Battle for Recombinant Factor VIII* 26 February 1998 p1 HSOC0016980

1558 Written Statement of Dr Paul Giangrande para 97.1 WITN3311003. See the chapter on *Access to Treatment*.

From early 1998, all cases of vCJD reported to the NCJDSU and diagnosed as having “probable” vCJD (not simply “confirmed” cases) resulted in a search of blood donation records to enable the destruction of any products made from those donations.<sup>1559</sup>

1998 is important for the taking of two major precautions: the actual start of the previously agreed programme of leucodepletion, and the acceptance of a recommendation not to use UK-sourced plasma to make blood products (instead, plasma for this purpose was to be imported).

As to the first, on 17 July 1998, the risks of transmission were determined to be high enough to justify starting a “£70 million” programme of removing most of the white blood cells from blood destined for transfusion: it became universal to the UK by October 1999.<sup>1560</sup>

As to the second, on 30 April 1998 the Committee on the Safety of Medicines recommended: *“that manufactured blood products should not be sourced from UK plasma. Although it was accepted that some parts of the manufacturing process for blood products may separate prion proteins, the present state of the art means that these processes cannot be validated. Therefore the theoretical risk that nvCJD could be transmitted by blood products cannot be discounted.”*<sup>1561</sup> BPL and the Protein Fractionation Centre were to agree on a date after which no products would be made from UK plasma. The Government accepted that advice, and on 12 November announced a “£30 million programme” to ensure the use of UK-sourced plasma for the manufacture of blood products would be phased out, by the purchase of plasma from foreign sources believed to be BSE-free.<sup>1562</sup> From the end of 1999 no UK plasma was used.<sup>1563</sup>

This went further still. The principal source of the plasma from outside the UK necessary to make blood products was the US, where there were signs that large pharmaceutical companies were increasingly acquiring smaller plasma collectors. This posed a potential risk to the continuation of supplies of plasma to BPL at reasonable cost. Accordingly, in December 2002 the UK Department of Health purchased the largest remaining independent plasma collector – Life Resources Incorporated – to ensure the continuity of supply without needing to rely on UK-sourced plasma.<sup>1564</sup> It should be noted that this proactive step occurred before the first case of a person known to have contracted vCJD from transfusion

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1559 Department of Health Press Release Further Precautionary Measures on Blood Products Announced 26 February 1998 p1 HSOC0015101\_002, NBA Procedure for Responding to Information supplied by the CJD Surveillance Unit 14 August 1998 NHBT0008720\_002

1560 House of Commons Statement by the Secretary of State for Health: Development in vCJD p2 ABHB0000181

1561 Appendix 1 to minutes of Committee on Safety of Medicines meeting 30 April 1998 p1 DHSC0041250\_103

1562 House of Commons Statement by the Secretary of State for Health: Development in vCJD p2 ABHB0000181

1563 Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting 28 October 1999 pp2-3 NHBT0004333

1564 Department of Health Press Release *Department of Health Secures Guaranteed Long-Term Supplies of Plasma for NHS Patients* 17 December 2002 HCDO0000266\_021

was reported. It involved time, effort and expense in order to take precautions against a threat which, though theorised, had never as yet materialised.

To return to the chronological story: in August 2000 the CMO (England), on behalf of the CMOs of all four nations, set up the CJD Incidents Panel (“CJDIP”). It was asked to develop a framework for the management of possible exposures to CJD through medical procedures which would then be subject to consultation with interested bodies and organisations.<sup>1565</sup> This framework document was not published in its first edition until March 2004 and some sections – including establishing a confidential database without consent, estimates of the infectivity of blood components and plasma derivatives, and “*Advice on the investigation and management of incidents involving blood*” – were “greyed out” as they had not yet been finalised.<sup>1566</sup> Consultation took place in the interim two and a half years or so. Much of that focussed on ethics and the risks and benefits to patients.<sup>1567</sup> Before the framework document was established, however, the CMOs of each of the four nations were asked to approve it. They responded in June 2003.<sup>1568</sup> Yet it was not for another nine months that the document was first published: during that interim, as described below, a highly significant event occurred.

## The first death from vCJD linked to a transfusion

The account so far is that once it was suspected that BSE might have spread to humans, precautions were taken progressively to lessen the risk of transmission of vCJD through blood. These were:

- (a) screening donors to exclude riskier donations
- (b) recalling products made from batches to which someone later found to have had CJD had donated, and destroying them
- (c) conducting a “lookback” to check if people with CJD had themselves received blood or blood products and if so from whom, and then if donations from those later shown to have CJD had caused symptoms in recipients

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1565 Letter from Professor Michael Banner to Professor Sir Liam Donaldson 4 October 2002 DHSC0004806\_026, CJD Incidents Panel *Management of possible exposure to CJD through medical procedures* 10 October 2001 NHBT0096710\_001

1566 CJD Incidents Panel *Management of possible exposure to CJD through medical procedures: Framework Document* 15 March 2004 p6, pp30-37, pp44-45, pp46-48 PHEN0000383. The framework drew particularly on two risk assessments: one in respect of the *Risk Assessment for Transmission of vCJD via Surgical Instruments: A Modelling Approach and Numerical Scenarios* by the Economics and Operational Research Division of the Department of Health; and the second in respect of the *Risk Assessment of Exposure to vCJD Infectivity in Blood and Blood Products* produced by Det Norske Veritas for the Department of Health. Department of Health *Risk Assessment for Transmission of vCJD via Surgical Instruments: A Modelling Approach and Numerical Scenarios* January 2001 HSSG0000136\_043, Det Norske Veritas *Risk Assessment of Exposure to vCJD Infectivity in Blood and Blood Products for Department of Health* February 2003 MHRA0007248

1567 “*The Panel debated the ethical impact of its decisions many times over the years*” was how Dr Nicola Connor put it in her written statement. Written Statement of Dr Nicola Connor para 20 WITN7091001

1568 Letter from Professor Sir Liam Donaldson to Professor Banner 9 June 2003 HCDO0000108\_106



- (d) adopting leucodepletion
- (e) phasing out the use of UK-sourced plasma in the manufacture of blood products
- (f) using recombinant factor concentrates for some patients

Some of these precautions involved considerable expense and effort. Yet at the time they were adopted the risk of transmission from one person to another through blood or blood products was purely theoretical. There had been no known case of it happening in the seven years since it had become known that BSE caused vCJD in humans. In sharp contrast with both clinical and governmental reaction in the early 1980s to the risk of AIDS, the argument that there was no conclusive proof to show that blood transmitted the cause of the disease was not rolled out to justify inaction. Rather, the approach was to act first, just in case, even if it later turned out that some measures might have been unnecessary.<sup>1569</sup>

Things changed in 2003. On 17 December 2003 the Secretary of State for Health, Dr John Reid, told Parliament that earlier in the autumn a patient had died. He had received a donation of blood in March 1996 from an infected donor. That donor died some three years later of the disease. Dr Reid announced that: *“In the light of the facts which I have outlined, it is therefore possible that the disease was transmitted from donor to recipient by blood transfusion, in circumstances where the blood of the donor was infectious, three years before the donor developed vCJD, and where the recipient developed vCJD after a six and a half year incubation period. This is a possibility not a proven causal connection.”*<sup>1570</sup>

This possible case led to further precautionary measures, announced immediately. 15 people who had received transfusions of blood from donors who subsequently developed vCJD were to be told. Those who had received blood products made from human plasma, and were concerned that it may have contained vCJD prions were invited to call NHS Direct. The MSBT was asked to reassess whether donors who had previously received a transfusion should be permitted to donate blood. The MSBT was to discuss with the Medical Royal Colleges and NHS hospitals reducing the use of blood transfusions to situations where it was absolutely necessary for medical reasons – measures to achieve this had only been partially successful before then.<sup>1571</sup>

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1569 Dr Angela Robinson, who was the National Blood Authority’s Medical Director at the time, described the change in approach as follows: *“There was a shift around the time of vCJD when the concept of the ‘precautionary principle’ was introduced. At that stage we were doing enormous things at great cost which we had not done before”* and she attributed that to the CMO Dr Kenneth Calman. Written Statement of Dr Angela Robinson para 306, para 311 WITN6926001. Dr Gail Miflin became Medical Director of NHSBT in 2016 and thought the response was also informed by earlier blood-borne infections, with the precautionary approach partly: *“as a result of the difficulty in testing blood for vCJD, and partly as a result of the experience of HIV and HCV in the preceding decades.”* Written Statement of Dr Gail Miflin para 1129 WITN0672006

1570 Statement of Secretary of State for Health regarding blood transfusion incident involving vCJD 18 December 2003 pp3-4 HCDO0000108\_005. The case was the subject of a written report: Llewelyn et al *Possible transmission of variant Creutzfeldt-Jakob disease by blood transfusion* The Lancet 7 February 2004 NHBT0008743\_013

1571 Statement of Secretary of State for Health regarding blood transfusion incident involving vCJD 18 December 2003 pp4-5 HCDO0000108\_005

The risk which had previously been purely theoretical may have manifested itself in practice. Further impetus was given to the need for precautions less than a week after Dr Reid's statement by the publication of research findings. The findings, of what came to be known as "the first appendix study", emphasised the risk. It suggested that there was a prevalence of infection of about 1 in 4,000 people, albeit from a study of limited size.<sup>1572</sup> These were people with no known symptoms whose appendices or tonsils showed an accumulation of the misfolded prion.<sup>1573</sup>

The MSBT met in January 2004. It agreed that any donor who had received a blood transfusion after 1 January 1980 should be excluded from donating.<sup>1574</sup> On 16 March 2004, Dr Reid made a ministerial statement accepting this recommendation.<sup>1575</sup>

## What should people be told of their personal risk?

The recognition of the first known case of transmission of vCJD by blood stimulated a reconsideration of whether those who received blood from a donor who had later been found to suffer vCJD should be notified of this,<sup>1576</sup> and indeed, whether to notify members of high-risk groups so that they did not donate blood, or have surgery without telling the surgeon of the increased risks there might be if surgical instruments used in their treatment were later used in the treatment of others.

The position which had been adopted back in 1996 was based on a number of factual premises. They are best illustrated by an exchange with Dr Patricia Hewitt, a member of the Standing Advisory Committee on Transfusion Transmitted Infections at the time it was proposing a study to check on recipients of those blood donors who later developed vCJD.<sup>1577</sup> Around May 1996 she spoke informally to Professor (now Sir Ian) Kennedy, then a professor of medical ethics at King's College London.<sup>1578</sup> He understood at the time that there was no evidence that vCJD was transmissible by blood transfusion; there was no screening nor diagnostic test; and no treatment to be offered to those infected. She remembered his advice as being that on balance it favoured not notifying identified recipients. He considers, now, that the lack of scientific evidence that vCJD was transmitted by blood transfusion at the time was "*crucial*". His view was and is that if such evidence became available, recipients should be identified and notified, since at that point their futures would be wholly changed,

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1572 Hilton et al *Prevalence of lymphoreticular prion protein accumulation in UK tissue samples* Journal of Pathology 2004 DHSC0006581\_004

1573 If infected there, the infection might then spread through the lymphoreticular system as described at the start of this chapter until it reached the brain.

1574 Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting 22 January 2004 p4 NHBT0035101

1575 Hansard extract on Developments in vCJD 16 March 2004 p1 DHSC0020695\_173

1576 See the MSBT's earlier approach in 1997, described above.

1577 Minutes of Standing Advisory Committee on Transfusion Transmitted Infections meeting 16 April 1996 p7 NHBT0000088\_013

1578 She mentions this in a letter to Professor Kennedy: Letter from Dr Hewitt to Professor Kennedy 15 April 1999 NHBT0017407

and they were entitled to know that.<sup>1579</sup> He is clear that if it were ever established that vCJD could be transmitted through blood transfusions it would be wrong not to inform recipients. He stated that his general view is that, ordinarily, people/patients should be informed if there is a reason to believe they are at risk as regards emerging diseases. This is the case notwithstanding the fact that there is nothing that they can do in terms of treatment in response to the information because “*once informed, they can at least adjust their lives and their relationships with others.*”<sup>1580</sup> Though he does not now recall the conversation, Dr Hewitt’s recollection closer to the time was that indeed he raised two important caveats – that if there was any change in the capacity to diagnose the disease, or if any intervention was possible, then the means to contact infected recipients must be in place.<sup>1581</sup>

Dr Hewitt wrote some three years later to Professor Kennedy, mentioning the conversation. By then the relevant circumstances had changed. A decision had been taken not to allow recipients of blood from people who later developed vCJD to become blood donors themselves.<sup>1582</sup> In his evidence to the Inquiry Professor Sir Ian Kennedy commented (rightly, and obviously) that that contemplated a scenario in which a number of those recipients would be informed that they had received blood from someone who later developed vCJD:

*“Quite apart from the relevant ethical questions in 1996 (which may or may not be answered differently in 1999 given the change of facts) there was a fundamental shift in the analysis. It was no longer a question of **whether** recipients should be informed, but instead, given that they (or some of them) will be informed given the policy at the time, **how** should they be informed? The answer to that, of course, is as carefully and sensitively as possible.”*<sup>1583</sup>

It is plain that had Professor Kennedy been available to respond to the letter (he was not)<sup>1584</sup> his advice would have changed diametrically from his earlier informal advice as recorded in that letter, because the circumstances were now so different.

The Lothian Research Ethics Committee initially took the view that no attempt should be made to trace nor inform recipients of implicated donations, and after being asked to review its position in October 1997, reiterated its earlier advice. It took the view that it was possible that the very act of advising a recipient in such circumstances would itself be construed as an injury given the mental suffering that would undoubtedly result and the probable impact on the recipient’s status with regard to life/healthcare insurance.<sup>1585</sup> By the end of 1997, an

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1579 Written Statement of Sir Ian Kennedy para 46 WITN7007001

1580 The central principle which Sir Ian Kennedy describes himself as applying was the ethical principle of concern for the rights and interests of people/patients. In the vast majority of circumstances that would mean that people are to be informed of what is contemplated by way of healthcare so they can decide for themselves what they wish to do. Written Statement of Sir Ian Kennedy para 15 WITN7007001

1581 Letter from Dr Hewitt to Professor Kennedy 15 April 1999 p1 NHBT0017407

1582 Letter from Dr Hewitt to Professor Kennedy 15 April 1999 p2 NHBT0017407

1583 Emphasis in the original. Written Statement of Sir Ian Kennedy para 47 WITN7007001

1584 He was chairing the public inquiry into children’s heart surgery at the Bristol Royal Infirmary. Written Statement of Sir Ian Kennedy para 42 WITN7007001

1585 SACTTI Position Statement 16 December 1997 NHBT0004115

awkward position had been reached in which it had been agreed: (a) to question donors in relation to any family history of CJD, (b) to investigate whether people with CJD had ever received transfusions or given blood, (c) to conduct a lookback to identify recipients of blood donations from donors who subsequently developed CJD, and (d) to recall batches of blood products to which someone with vCJD had contributed,<sup>1586</sup> and yet it had also been agreed that no one should be told that they were at risk of either transmitting or themselves developing vCJD (or both) and why. When the blood services were informed of suspected cases of vCJD from any sources which were then confirmed by the NCJDRSU, the recipients would have to be traced – but not informed. The advice had been accepted that the leucodepletion of blood and blood products should be extended in order to protect the public against risk. In short, serious and costly steps to protect public health were taken on the basis that there was a real risk that blood and blood products **might** transmit the cause of vCJD – yet no attempt was to be made to advise individual recipients that that real risk applied in particular to them.

It is difficult, in principle, to justify a position based on there being no scientific evidence that a disease can be transmitted by blood and blood products (ie no meaningful risk) as a basis for dealing with patients whilst recognising that there is such a risk when introducing measures to protect public health. A sensible policy should not look in opposite directions at one and the same time.

A practical difficulty was recognised in applying the policy of non information. To meet the public health risk blood products might have to be recalled from patients. What should they be told? The advice from the NHS Executive to NHS medical directors on 6 February 1998 was that they had been told by ethics experts and advisory bodies that there was no need to inform patients of their exposure because:

- it was thought unlikely that vCJD would be transmitted this way
- there was no diagnostic test for vCJD
- there was no preventative treatment for vCJD

*“In these circumstances the general view is that patients will not benefit from this knowledge, and that uncertainty created by informing patients could have the contrary effect causing unjustified worry and creating a permanent blight on their lives in relation, for example, to obtaining life or health care insurance.”* The advice then added that it was for individual

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<sup>1586</sup> Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting 27 October 1997 p3 SBTS0000522

clinicians to decide whether to follow the ethical advice.<sup>1587</sup> A letter in identical terms was sent by the Scottish Office to NHS trust medical directors on 23 April 1998.<sup>1588</sup>

What was to be said to those who came to donate blood and were told it could not be accepted? Professor Len Doyal wrote to Dr Hewitt of the National Blood Authority expressing his view that donors who were told their blood would not be used must be informed why that was, and that it would be illegal and immoral to allow someone to give blood when it was known that the donation would be destroyed. He identified the inconsistency:

*“The problem is that the National Blood Authority has adopted a policy about the non-use of the blood of the recipients of potentially infected blood which entails that they must be informed that they are ineligible to give it. The Department [of Health] has also insisted that as the medium of potential transmission, white cells be removed from blood for transfusion. Both decisions suggest – and will certainly do so to the public – that there is evidence of transmissibility. Therefore, recipients or donors who are told that their blood cannot be used must be informed of the circumstances surrounding this decision. On the one hand, if they are given no explanation then they will rightly demand it. On the other hand, if they are told nothing and allowed give [sic] blood which is then simply destroyed, they would be doing so under false pretences. This is both immoral and illegal. If any thing should now be clear in the practice of health care in Britain, it is that deception is not an option for good clinical practice or public policy.”*<sup>1589</sup>

At the same time as Dr Hewitt had been speaking to Professor Doyal, the MSBT discussed how to manage donors known to have received blood from people who subsequently developed vCJD. In January 2000 the outcome was reported to Dr Angela Robinson in her role as medical director of the National Blood Authority. Although the letter recognised the current Department of Health policy that people who might have been exposed to vCJD through blood or blood products should not be informed of this, it said that that policy would be kept under review. It was noted that MSBT had agreed that “*in the spirit of openness*” and “*contracts with donors*” the blood services would need to consider telling, or offering to tell, the donor why their blood could not be accepted. However, discussions with such donors

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1587 Letter from Dr Graham Winyard to NHS Trust medical directors 6 February 1998 p1 BART0002418. The full text deserves citation. It adds: “*There may clearly be some circumstances where clinicians will decide to inform a particular patient of the reason for the product withdrawal, for example where a product involved in the recall is one that is generally held by the patient at home, or where the recall action has prompted an individual patient specifically to ask whether he/she has received the implicated blood product. In such circumstances it is for the clinician to decide how best to respond, having taken careful consideration of all aspects of his/her patients circumstances.*” Letter from Dr Graham Winyard to NHS Trust medical directors 6 February 1988 p2 BART0002418. By saying what it did the NHS Executive might arguably be telling clinicians they were free to act unethically: although it must be true that each patient’s case is individual, and the treatment should be appropriate to the individual, so that other ethical considerations may come into play, this possibly represents a reluctance to interfere too much with “clinical freedom”.

1588 Letter from Sir David Carter to NHS Trust Medical Directors 23 April 1998 GGCL0000111\_001

1589 Letter from Professor Doyal to Dr Hewitt 20 December 1999 p2 NHBT0004392\_002



were to be managed on a case-by-case basis, and the appropriate health department contacted in the first instance. A protocol to deal with this was to be developed.<sup>1590</sup>

In the meantime the continuing debate about whether or not people should be told that they had an increased risk of developing vCJD had a chilling effect on the continuation of the Transfusion Medicine Epidemiology Review (“TMER”) study to examine a possible connection between transfusion and the development of vCJD. On 30 January 2000 the Lothian Research Ethics Committee refused the NCJDRSU’s application for renewed ethical approval of the TMER.<sup>1591</sup>

Professor Will of the NCJDRSU made a further application on 23 May 2000 to reconsider ethical approval for the TMER on the basis that it was unethical not to do the study because it might be the only mechanism by which transmission of vCJD through blood or blood products could be identified.<sup>1592</sup> On 31 May 2000, in response to this, the Lothian Research Ethics Committee then reinstated approval for the TMER – but this was on the basis that the decision whether to inform a person identified as being at risk by the TMER was left to the local health authority.<sup>1593</sup> For four months the study had been without ethical approval.

In June 2000 the options were discussed at a meeting. It was agreed, after what the minutes suggest was a wide-ranging discussion, that the questionnaires which were always completed regarding a donor’s medical history should have a question built into them which would effectively allow patients to make an informed choice about whether they would like to be told of risks to their health. They would be told that their blood could be rejected for a range of reasons from the very minor to a major health concern. It also agreed that full counselling would be available to the patient if they made the decision to be informed of any risk to their health that emerged.<sup>1594</sup>

As part of risk management the CJDIP sought to balance the individual’s “*right to know*” and “*right not to know*” about possible exposure to risk.<sup>1595</sup> Although the CJDIP were close to finalising their framework for the management of possible exposures to CJD through medical procedures for publication by the time the Secretary of State announced in December 2003 that 15 people would be informed that they had received transfusions from donors who subsequently developed vCJD, the section on managing blood incidents was marked as not yet finalised.<sup>1596</sup> The Department of Health asked the Health Protection Agency (“HPA”) to take the lead in notifying people. The HPA were informed about 19 people who should be notified, 2 of whom were in Scotland and 2 of whom transpired to have died. The HPA

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1590 Letter from Dr Mike McGovern to Dr Robinson 12 January 2000 NHBT0004310

1591 Letter from Dr Ian Starkey to Professor Robert Will 30 January 2000 NHBT0004364\_004

1592 Letter from Professor Will to Dr Ian Starkey 23 May 2000 p2 NCRU0000112\_068

1593 Letter from Dr Ian Starkey to Professor Will 31 May 2000 p1 NCRU0000112\_069

1594 Minutes of NHS Blood and Transplant meeting 16 June 2000 pp5-6 NHBT0009063\_002

1595 Minutes of NHS Blood and Transplant meeting 16 June 2000 p4 NHBT0009063\_002

1596 CJD Incidents Panel *Management of possible exposure to CJD through medical procedures Framework Document* Draft 1 December 2003 pp47-49 DHSC0020839\_003, Statement of Secretary of State for Health regarding blood transfusion incident involving vCJD 18 December 2003 p4 HCDO0000108\_005

decided that the local health protection team and the GP should decide the most appropriate way to inform and support each person.<sup>1597</sup>

Mark Buckland was a young man who was infected with vCJD in September 1997 as a result of receiving a blood transfusion during surgery. He received a letter from the HPA in early January 2004 as part of the national notification exercise, informing him that he had been identified as having received a significant volume of blood transfusions that carried a theoretical risk of vCJD.<sup>1598</sup> Mark's father, Peter Buckland, subsequently discovered that the blood service had known since 18 August 2000 that one of the donors of a unit transfused into his son in 1997 had died of vCJD.<sup>1599</sup> Dr Hewitt explained that the initial decision not to inform recipients was made by the Department of Health.<sup>1600</sup>

The impact of the delay in informing Mark Buckland of this was considered during the inquest into his death. The Coroner heard (from Dr Stephen Wroe, a consultant neurologist) that had Mr Buckland been in regular contact for review with the National Prion Clinic then the diagnosis of vCJD would have been made between 6 and 18 months earlier than it was. This in turn would have allowed Mark Buckland's earlier entry onto the trial of quinacrine. Moreover, earlier information would have allowed Mark, his family and friends more time to come to terms with the diagnosis rather than being left to struggle with an (erroneous) diagnosis of chronic fatigue syndrome. It was Dr Wroe's view, which was shared by the Coroner, that Mark Buckland should have been informed that he had received blood from a donor with vCJD as soon as the Department of Health became aware of that fact in 2000. As the Coroner explained, "*patients should have the opportunity of receiving appropriate assessments, advice and treatment if they wish and being able to deal with the possible future, doing what they may wish to do and helping their families to come to terms with the future as well.*"<sup>1601</sup> Mark's father Peter told the Inquiry that withholding the information from Mark was wrong: "*he would have thought to himself, 'Okay, if this is the case and I don't know, but if this is the case I'll make sure I live a full life', I would have told him to do that, instruct him, I'm sure he'd have thought the same. At least he would have known the truth.*"<sup>1602</sup>

1597 Health Protection Agency CJD Team *Interim Report on incident involving blood components and vCJD and the patient notification exercise conducted from December 2003 to January 2004* 21 January 2004 pp4-9 PHEN0000104. Following the diagnosis of vCJD in two more former donors, another ten people who had received transfusions were notified in 2005. Minutes of CJD Incidents Panel meeting 7 September 2005 pp6-7 PHEN0000629

1598 A copy of a similar letter and a patient information sheet is at Letter from Health Protection Unit to Patients 31 December 2003 PHEN0002392\_005, Health Protection Agency CJD Team *Interim Report on incident involving blood components and vCJD and the patient notification exercise conducted from December 2003 to January 2004* 21 January 2004 pp27-28 PHEN0000104

1599 Peter Buckland Transcript 6 June 2019 pp71-73 INQY1000015

1600 Written Statement of Dr Patricia Hewitt para 11 WITN3101002. This advice is recorded in the letter set out above: Letter from Dr Graham Winyard to NHS Trust medical directors 6 February 1998 p1 BART0002418

1601 Written Statement of HM Deputy Coroner for Brighton & Hove Arthur Hooper 16 August 2006 p6 WITN0694008. The Coroner wrote to the Secretary of State for Health to express his concern that Mark Buckland had not been told of the position at the earliest possible stage. Letter from Arthur Hooper to Dr Patricia Hewitt 26 September 2006 p4 WITN0694002. Caroline Flint responded on behalf of the Secretary of State. Letter from Caroline Flint to Arthur Hooper 12 October 2006 PRIU0000015

1602 Peter Buckland Transcript 6 June 2019 p74 INQY1000015

It was not known in 1997, when Mark Buckland was transfused, that the donor suffered from vCJD. It was known in 2000. By then, the risk that blood transfusions might transmit vCJD was understood, sufficiently for the several measures set out above to have been taken to protect people from this happening. Given this, given what Professor Doyal said in 1999, given the views that Professor Sir Ian Kennedy has, then I am clear that these views of Dr Wroe, the Coroner and Peter Buckland, are right. Dr Hewitt now feels that the blood services may have been “*erring on the side of not acting soon enough to impart potentially devastating news in terms of possible exposure to HCV and vCJD.*”<sup>1603</sup> She too is right.<sup>1604</sup>

Half a year after the first set of notifications to people who had received transfusions, the CJDIP produced a report in July 2004 recommending which groups should be told they had an increased risk of vCJD for public health purposes from implicated plasma, and setting out notification timelines.<sup>1605</sup> This referred to the announcement the previous December of the first transfusion-related case of vCJD. So far as patients who received plasma products were concerned, they were regarded as being “at risk” if they were assessed as having received sufficient blood products to be considered exposed to a 1% or greater risk of infection, on top of the general risk to the UK population from eating beef.<sup>1606</sup>

## More cases come to light

A second case of transfusion-related vCJD was reported in July 2004.<sup>1607</sup>

On 7 September 2004, the CJDIP finalised their advice, with a three-stage categorisation of the likelihood of patients being “at risk” of vCJD for public health purposes – “*High*”, “*Medium*” or “*Low*”. “*High*” was where the amount of potential infectivity was high enough for patients to be considered “*at-risk*” following the administration of a very small dose (eg one treatment with Factor 8 or 9); “*Medium*” where the amount of potential vCJD infectivity in product batches was not low enough to be ignored but substantial quantities of the material

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1603 Written Statement of Dr Patricia Hewitt para 105 WITN3101006. Dr Hewitt told the Inquiry that “*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.*” In her oral evidence she referred to another case where a recipient developed vCJD, whose family had said that “*If they had known that he had been at risk, his last few months would have been dealt with differently ... they would have known what they were dealing with, or what they were likely to be dealing with.*” Dr Patricia Hewitt Transcript 10 December 2021 p129 INQY1000171

1604 However, because the question is essentially an ethical one, I think she is being too careful in introducing her view with the words “*With hindsight*”. Though the answer to ethical questions may often be difficult to tease out, they were expressed at the time; they were capable of being expressed at the time; and in this case – that of the failure to notify Mark Buckland earlier – the proper course was not followed.

1605 vCJD and Implicated Plasma Products Notification Road Map 23 July 2004 LOTH0000082\_007

1606 The threshold of 1% was consistent with the threshold for patients exposed through surgical instruments. Report on Notification of potential exposure to vCJD through plasma products 7 January 2005 p5 PHEN0000721

1607 See: Health Protection Agency *Variant Creutzfeldt-Jakob Disease (vCJD) and Plasma Products: Clinical Information 7* September 2004 p2 HCDO0000650, House of Commons Notice of Written Ministerial Statement on Blood Donation and vCJD 9 September 2004 p2 HCDO0000660

would need to be administered for patients to be considered “*at-risk*” (eg several infusions of intravenous immunoglobulin, or large doses of albumin 4.5%); “*Low*” where the amount of infectivity was so low that the likelihood of the patient being considered at potential additional risk of vCJD could realistically be ignored. These were specifically thresholds for public health purposes, and not estimates of assessed individual risk.<sup>1608</sup> CJDIP also wrote to those responsible for tracing vCJD-implicated plasma batches setting out tables of implicated batch numbers.<sup>1609</sup>

Two days later, Dr Reid, the Secretary of State for Health, announced in Parliament that clinicians had been given the information to enable them to identify potentially infected batches, and said that they would then as a precaution notify any patient identified as “at risk” as having received product from that batch. He commented: “*Although there are now two reports of possible transmission of vCJD via blood, the risk of transmission via plasma products, which will have been derived from large pools of plasma donated from many thousands of people - and therefore heavily diluted - is uncertain. But it cannot be excluded.*” He added that: “*Throughout this exercise we have been concerned to ensure that the results of the risk assessment are communicated to patients by the clinicians responsible for their day to day care, so that appropriate supporting information can be provided.*”<sup>1610</sup>

The HPA and the Scottish Health Protection Centre for Infection and Environmental Health (“SCIEH”) had consulted on how to notify patients:

*“The UKHCDO and Haemophilia Society argued that since a single dose of implicated plasma concentrate would be sufficient to place a recipient ‘at-risk’ and because future batches were likely to be implicated ... all patients with bleeding disorders treated with UK-sourced pooled factor concentrates or antithrombin between 1980 and 2001 should be considered ‘at-risk’ and asked to take public health precautions, rather than just those who had received the known implicated batches”*.<sup>1611</sup>

People with a bleeding disorder were informed by their haemophilia centre in September 2004 and given an opportunity to discuss the implications and to find out if they had received an implicated batch if they wished.<sup>1612</sup>

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1608 Assessment of exposure to particular batches of variant Creutzfeldt-Jakob disease (vCJD) implicated plasma products 7 September 2004 HCDO0000647

1609 Note addressed to those responsible for tracing vCJD implicated plasma product batches in the UK 7 September 2004 HCDO0000649

1610 House of Commons Notice of Written Ministerial Statement on Blood Donation and vCJD 9 September 2004 pp2-3 HCDO0000660

1611 The UK Primary Immunodeficiency Network preferred an individual approach of informing only those patients who had received an implicated batch. Report on Notification of potential exposure to vCJD through plasma products 7 January 2005 pp7-9 PHEN0000721

1612 See for example letters sent by the Newcastle Haemophilia Centre, including a leaflet jointly produced by the HPA, SCIEH, National Public Health Service for Wales and the Northern Ireland Department of Health, Social Services and Public Safety. Letters from Dr John Hanley and Dr Kate Talks to Patients or Parents 20 September 2004 NTHT0000012. Letter from Dr Frank Hill to Haemophilia Centre Doctors 9 September 2004 HCDO0000658. See also the evidence of Professor Charles Hay who

By January 2005 the HPA reported that approximately 4,000 people with bleeding disorders had been told they were at risk from vCJD, and that it had identified 12 other patients who by reason of their conditions and exposure to plasma products were at sufficient risk to require public health precautions to be taken (notifying them, so that they could then notify their families and any treating doctor). By this time, 9 plasma donors were known to have developed vCJD and had made 23 blood donations which had been made into 187 batches of various plasma products.<sup>1613</sup>

By July 2005 it had been identified that three patients had developed vCJD almost certainly as a consequence of receiving blood transfusions. Between them, they had received the blood of 110 donors. Those then had to be traced, and advised that they should not give any further donations, nor should their tissues or organs be donated.<sup>1614</sup>

In January 2007 a fourth case of vCJD transmission was associated with blood transfusion and was reported to the press.<sup>1615</sup>

Thus far, despite the umbrella approach which had been taken for notifying everyone with a bleeding disorder who had attended a haemophilia centre for treatment between 1980 and 2001 that they were “at risk”, none of the identified cases related to a person with a bleeding disorder. However, on 7 September 2009 it was confirmed that a post mortem carried out on a man with haemophilia found the vCJD prion in his spleen. He did not die of vCJD; nor was it present in the brain. However, the probability was that he had been infected and that the likeliest cause was his treatment with a plasma product.<sup>1616</sup> An early report of this case in *The Sunday Telegraph* on 15 February 2009 prompted an update being urgently sent to people with bleeding disorders saying that “*The information from this case does not change the public health ‘at risk’ status of any patients with bleeding disorders*”.<sup>1617</sup>

Whereas people who had received transfusions were only notified if a donor went on to be diagnosed with vCJD, patients undergoing surgery or endoscopy were now to be asked if they had received blood transfusions from 80 or more donors since 1980 and considered at increased risk if so.<sup>1618</sup>

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was vice chair of UKHCDO in 2004 and later chair. Written Statement of Professor Charles Hay paras 144.1-150.2 WITN3289039

1613 Report on Notification of potential exposure to vCJD through plasma products 7 January 2005 p2, pp15-16 PHEN0000721. On individual assessment, none of the patients with primary immunodeficiencies were assessed to be at-risk for public health purposes.

1614 Hewitt et al *vCJD Donor Notification Exercise: 2005* Clinical Ethics 2006 p1, p7 RLIT0000156

1615 Health Protection Agency Draft Press Release *4th case of variant CJD infection associated with blood transfusion* 16 January 2007 HCDO0000131\_006

1616 The surveillance form is dated the same day: UKHCDO/Department of Health surveillance form 7 September 2009 p2 HCDO0000131\_056. Written Statement of Professor James Ironside para 8(a) viii WITN7034001, Peden et al *Variant CJD infection in the spleen of a neurologically asymptomatic UK adult patient with haemophilia* Haemophilia 2010 pp4-6 HCDO0000799

1617 Email chain entitled vCJD running on Telegraph website 15 February 2009 15 February 2009 pp3-4 DHSC5198184, Template letter from UK Haemophilia Centre Doctors to patients February 2009 p8 CVHB0000011\_015

1618 Letter from Dr Hester Ward, Mr David Pryer and Professor Jeffries to Chief Executives of NHS Boards July 2009 p1 RLIT0001222



In July 2011 the Advisory Committee on Dangerous Pathogens Transmissible Spongiform Encephalopathy Risk Assessment Sub-Group met for the first time. It advised the Department of Health that the policy adopted thus far had relied on the precautionary principle, and was thus largely driven by the “*worst case’ scenarios*”. It was not surprising that there would be changes as more information accrued over time. Prediction of future infection would change, and policy would evolve accordingly. The models which had been used to predict the risk of future infection indicated rates of infection which were higher than those actually seen. There might thus be a need to adjust the models to account for this.<sup>1619</sup>

A consequence of this reasoning, and a subsequent paper from the Department of Health recalculating the level of risk,<sup>1620</sup> was that in 2013 those who had received plasma products only between 1980 and 1989 should be de-notified – ie told they need no longer consider themselves as more of a risk than other members of the public, and need not declare any additional risk to doctors or dentists as they had been doing.<sup>1621</sup>

By 2013, 11 patients who had received transfusions from more than 80 donors and were due to undergo surgery had been identified.<sup>1622</sup> The threshold was revised by 2014 so that only patients who had received transfusions donated by an aggregate total of 300 or more donors were to be considered at risk for public health purposes.<sup>1623</sup>

By mid summer 2014, it appeared that the worst fears of a rapid rise in the number of cases of vCJD had not been realised. It seemed possible to entitle an official report by the House of Commons Science and Technology Committee on UK blood safety and the risk of vCJD: “*After the storm?*” But what remained uncertain was also recognised: there was a question mark after the word “*storm*”.<sup>1624</sup> The report concluded:

*“in the vast majority of cases, the benefits of receiving a transfusion will far outweigh the risks of acquiring a transfusion-transmitted infection. However, we urge against complacency and stress the need for UK Blood Services to remain vigilant to the threat posed by blood-borne pathogens ... We consider it imperative that a precautionary approach to [the risk that prions remain present in the blood supply] be maintained until further evidence becomes available ... Pathogens are constantly emerging and evolving; novel pathogens will therefore always pose a threat to the blood supply. In the past, it has often taken multiple cases of transfusion-transmitted infection before these threats have been recognised*

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1619 Minutes of Advisory Committee on Dangerous Pathogens Transmissible Spongiform Encephalopathy meeting 14 July 2011 pp6-7 DHSC5235271

1620 Blood-Borne Transmission of vCJD: Revisions to Risk Assessment 31 August 2011 PHEN0000600

1621 Letter from Dr Katy Sinka to Dr Gerard Dolan 24 January 2013 WITN3775004, Letter from Dr Dolan to UKHCDO colleagues 25 April 2013 pp3-5 LGFT0000020

1622 Written Statement of Dr Nicola Connor para 103 WITN7091001

1623 ie the aggregate of the number of single units they had received, many of which might have been given on repeated occasions: the reference to “donors” indicates that some multiply transfused patients may have received more than one unit from the same donor, but this only counted once. Template letter from Dr Sinka to doctors of patients at increased risk of vCJD 2014 WITN7091009

1624 The full citation is: House of Commons Science and Technology Committee *After the Storm? UK blood safety and the risk of variant Creutzfeldt-Jakob Disease* 24 July 2014 TSTC0000052

*and mitigated. This will remain the case as long as risk mitigation measures remain pathogen-specific. We urge the Government to take steps to support the development of broader spectrum technologies with the potential to mitigate the risk of both known and unknown pathogens.”*<sup>1625</sup>

In its final paragraph the Committee wrote:

*“We conclude this report by recommending that the Government take a more precautionary approach to both vCJD risk mitigation and blood safety more generally, in order to safeguard against future infections. We suggest that it begin by assessing the key risks, known and unknown, that the UK blood supply currently faces and might face in the future, so that it can identify and fill relevant knowledge gaps and support the development of appropriate risk reduction measures and technologies.”*<sup>1626</sup>

## The position as at the date of this Report

There have been 178 cases of vCJD in the UK identified as definite (supported by post mortem) or probable (no post mortem), though the latter category is virtually certain.<sup>1627</sup> No new case of vCJD has been identified since 2016.<sup>1628</sup> No one now living in the UK has been diagnosed with vCJD.

Although no case of vCJD has manifested itself since 2016, a review of three studies conducted between 1995 and 2014 of the prevalence with which abnormal prion proteins seen in samples of appendices removed at operation (hence “*appendix studies*”, as they are known) found that 1 in 2,000 of the population had abnormal prion protein in their appendix.<sup>1629</sup> The exact implications of this remain unclear.<sup>1630</sup> Thus it is not known whether these individuals are in a carrier state, such that they might unwittingly pass on the abnormal proteins through the use of surgical instruments, or by giving blood – though as to the latter, leucodepletion seems to have successfully prevented this happening so far.

Leucodepletion was, however, introduced too late to prevent the transmissions which occurred in the four symptomatic cases in which there has been known to be transmission

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1625 House of Commons Science and Technology Committee *After the Storm? UK blood safety and the risk of variant Creutzfeldt-Jakob Disease* 24 July 2014 p53 TSTC0000052

1626 House of Commons Science and Technology Committee *After the Storm? UK blood safety and the risk of variant Creutzfeldt-Jakob Disease* 24 July 2014 p57 TSTC0000052

1627 Professor James Ironside Transcript 17 May 2022 p28 INQY1000207

1628 NCJDRSU 26th Annual Report 2017 Creutzfeldt-Jakob Disease Surveillance in the United Kingdom 2017 p11 RLIT0001605, Expert Report to the Infected Blood Inquiry: Statistics September 2022 p95 EXPG0000049

1629 Diack et al *Public health risks from subclinical variant CJD Public Library of Science Pathogens* 30 November 2017 p2 RLIT0002363

1630 Written Statement of Professor Robert Will pp34-35 WITN7098001

of vCJD via blood and blood components, and the one other case which was via blood products and asymptomatic.<sup>1631</sup>

Research has shown that there is genetic variation between individuals relating to the make-up of the prion protein. One of two chemicals – methionine or valine – is involved. The possible combinations were likened by Professor Ironside in his evidence to those of blood groups: just as blood may be grouped, as A, B, AB, or O depending upon the genetic coding of the individual concerned, so the prion protein may be MM, MV, or VV. In all but one case of vCJD so far identified, the patient has been MM. The current working supposition is that MM individuals are more likely to have the shortest incubation period, and VV the longest, with MV somewhere in between.<sup>1632</sup> If this is so, and if indeed some people who are asymptomatic are carriers who are capable of transmitting their abnormal prions, some of the risk may not yet have materialised. The prospects are encouraging, but vigilance remains essential.

## Steps as yet untaken: missed opportunities or steps too far?

It was apparent after 1997 that if the risk of transmissibility from one human to another were to be borne out in practice, there were two particular implications for public health.

First, there was a risk that surgical instruments used in abdominal surgery might transmit the disease from one person to another since prions stick “rather *avidly*”<sup>1633</sup> to the surface of surgical stainless steel. There was thus a risk that surgery on the gut and internal organs would, just as in the case of surgery on the brain, give rise to a risk of the transference of prion disease, unless the instruments could successfully be decontaminated. Second, it was essential to establish as accurately as possible in the UK those who were incubating prion disease even if they had not yet suffered symptoms, because in such a pre-symptomatic state they might unwittingly transmit the disease to others, and give rise to an epidemic.

Professor Collinge described how his unit<sup>1634</sup> addressed both concerns. First, his unit was directed in the early 2000s to research methods of decontamination, and was funded by the Government to do so. It developed by trial and error what he said could be thought of as a “*sort of biological washing powder*” which cleaned surgical instruments of prions – it was a mixture of enzymes which would break up proteins, together with things that enabled those enzymes to access the surface to be cleaned: a form of detergent with enzymes. He also was able to develop an assay which showed whether the “*washing powder*” had

1631 For details of these see the evidence of Professor Ironside: Professor James Ironside Transcript 17 May 2022 pp31-35 INQY1000207. See also: Expert Report to the Infected Blood Inquiry: Statistics September 2022 pp95-98 EXPG0000049

1632 Professor James Ironside Transcript 17 May 2022 pp23-25 INQY1000207

1633 Professor John Collinge Transcript 13 May 2022 p32 INQY1000206

1634 The Medical Research Council Prion Unit, established in 1998 at the University College London Institute of Neurology under Professor Collinge “*to provide a national centre of excellence with all necessary facilities to pursue a major long-term research strategy in prion and related diseases*”. House of Commons Science and Technology Committee *After the storm? UK blood safety and the risk of variant Creutzfeldt-Jakob Disease* 24 July 2014 p34 TSTC0000052

actually been effective in any given case in achieving decontamination. This showed that his unit had succeeded in developing a product which could show a reduction of prions on a metal surface by “*about a millionfold*”.<sup>1635</sup> It would best be used to soak instruments prior to autoclaving. For it to be produced in reasonable quantities at an acceptable cost for use by NHS Trusts required commercial involvement. DuPont, who had marketed a high-level disinfectant for surgical products called Rely+On Perasafe since 1998, were interested in incorporating the unit’s technology into it, by making Rely+On Prion Inactivator. In 2008 and 2009 the use of the product was evaluated by the Government’s Rapid Review Panel. This accepted that basic research and development had been completed, and that the product had “*potential value*” but should be further evaluated by trials in an NHS setting. In 2010, DuPont put further development of the product on hold, because it had proved difficult in practice to initiate a UK trial, and because the Rapid Review Panel indicated that because its use would involve a change of practice in established decontamination procedures it was unlikely to find widespread acceptance unless the risk of vCJD became a greater concern than it was by then.<sup>1636</sup>

The NHS has not adopted the use of this prewash product.<sup>1637</sup> Rather, their present approach is to rely upon quarantining surgical instruments to ensure that those on whom they had been used do not, within the quarantine period, show signs of CJD.<sup>1638</sup> This in turn has led to access to some surgical procedures being difficult for patients who are considered to be in a class which is generally at higher risk than the general public, in particular people with bleeding disorders and people who had multiple transfusions: the Inquiry has heard reports of Trusts being unwilling to conduct some operations (or of delaying operations) because of a worry that the expensive equipment required will have to be quarantined, meaning that further sets of the equipment would then need to be purchased for use in the meantime. They regard this as simply too expensive and inconvenient.<sup>1639</sup> It is plainly not acceptable that

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1635 Professor John Collinge Transcript 13 May 2022 pp67-70 INQY1000206

1636 House of Commons Science and Technology Committee *After the storm? UK blood safety and the risk of variant Creutzfeldt-Jakob Disease* 24 July 2014 pp22-25 TSTC0000052

1637 The reasons given by the Department of Health for this are set out in Morwenna Carrington’s statement. The product was not adopted by the NHS in 2007 “*as it did not achieve a category 1 rating from the RRP [Rapid Review Panel]. All manufacturers of products are required to have a category 1 rating to be suitable for the NHS. Other manufacturers developing similar pre-soaks also did not achieve a category 1 rating from the RRP and were not recommended for use in the NHS.*” Written Statement of Morwenna Carrington para 3.25 WITN7590001, NHS National Institute for Health and Clinical Excellence *Patient safety and reduction of risk of transmission of Creutzfeldt-Jakob disease (CJD) via interventional procedures* November 2006 SCGV0002357. It was not adopted later because (as it appeared to Morwenna Carrington from reviewing the documents on the evaluation of the pre-wash product), “*it appears that the product required further development to ensure adequate decontamination and implementation for use in the NHS. The product was not re-submitted for review and other companies did not achieve a category 1 rating. At that time, pre-soaks were not considered viable products for use in the NHS and, as it was not resubmitted and further development work was not continued by DuPont, it is my understanding that it was not implemented, and other decontamination methods were used.*” Written Statement of Morwenna Carrington para 3.33 WITN7590001

1638 Professor John Collinge Transcript 13 May 2022 pp70-72 INQY1000206

1639 Guidance was issued in 2006 by the Advisory Committee on Dangerous Pathogens’ Transmissible Spongiform Encephalopathy subgroup entitled “*Assessment to be carried out before surgery and/or endoscopy to identify patients with, or at increased risk of, CJD or vCJD*”, which was updated from time to time. The 2014 iteration of this guidance makes it clear that patient care should not

people who have been infected as a result of NHS treatment should then find themselves further disadvantaged and put at risk by having operations or investigations deferred or denied, and steps should have been taken to ensure that this does not continue to happen.

Second, the implication was that a test for the presence of the misfolded prion was needed. This was also achieved by Professor Collinge's team. In 2011, they reported the development of a prototype blood test to diagnose vCJD in symptomatic individuals which could be further developed into a large-scale screening test for asymptomatic vCJD prion infections. In trials on a US population, supposed to be free of vCJD (since the US was free of BSE) the tests produced no false positives. Data showed it was likely to detect successfully three out of every four cases of vCJD that came before it.<sup>1640</sup>

The test has remained as a prototype. In order to be rolled out as a screening test for blood the test kit would need to be manufactured on a commercial scale. A commercial company was unlikely to develop and market such a test without first seeing the results of a study comparing large populations of those people presumptively exposed to vCJD with those presumptively unexposed (a large-scale comparison of 20,000 to 50,000 people in the UK and 20,000 to 50,000 people in the US). A study of this size is costly. Professor Collinge found that companies would not invest in such a study without being assured that there was a sufficiently significant problem with prions in blood in the UK to create a profitable market for the test. His team were unable to secure a commercial partner to make such an investment. The Medical Research Council, which had funded the initial research, also failed to finance such a study. The House of Commons Science and Technology Committee report in 2014 considered that a vCJD prevalence study utilising a version of this prototype test would be *"of considerable value, both for test development and research purposes"*

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be prejudiced as a result of the procedures to be followed in identifying patients at an increased risk of vCJD. Annex J to Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infection August 2017 p1 WITN7080005. Despite this, the Inquiry has received many accounts of the impact of this. Barbara ANON described how her late husband, Leigh, was refused endoscopies after he was diagnosed with liver cancer in consequence of infection with Hepatitis C because he had received a notification letter about vCJD. *"We ended up paying thousands of pounds for Leigh to undergo the necessary procedures. It not only cost us money but it cost Leigh valuable time."* Written Statement of Barbara ANON p9 WITN2555001. Ian ANON needed his gallbladder removed having been infected with Hepatitis C and the surgeon told him *"You are an expensive patient. We had to archive everything in the theatre because you have a variant CJD risk"*. Ian said: *"I felt deeply embarrassed and dirty at the time."* Written Statement of Ian ANON para 21 WITN2072001. Another man was refused a liver biopsy as part of care for Hepatitis B and C. Written Statement of ANON para 112 WITN5343001. Another man infected with Hepatitis C told the Inquiry: *"The greatest impact of this whole saga has been the problems that I have experienced with regard to my suspected 'infection' with vCJD. Having been told that I was 'at-risk' for public health purposes in 2004 I noticed a significant change in how I was treated by the medical profession ... It happens so often and it drives me mad, especially because of the number of appointments I have to attend. I have been made to feel dirty and these last minute changes of plan are incredibly frustrating, not to mention the problems of actually physically getting myself to these places because of my other health issues ... It really upsets me."* Written Statement of ANON paras 38-51 WITN5407001. Mr AN told the Inquiry of having to insist upon procedures being carried out in the face of unwillingness from clinicians, and of then being made to wait around until the end of the patient list before being seen, and of having had procedures cancelled on the basis that there was no suitable equipment available. Mr AN Transcript 16 October 2019 pp32-33 INQY1000042, Written Statement of ANON WITN1387016

<sup>1640</sup> Edgeworth et al *Detection of prion infection in variant Creutzfeldt-Jakob disease: a blood-based assay* The Lancet 5 February 2011 NHBT0033626



and recommended that there be a large-scale vCJD prevalence study within the following 12 months – it considered other candidates, and concluded that Professor Collinge’s offer was the most promising.<sup>1641</sup> However, to date, this recommendation has not been given effect.

## The BSE Inquiry

Within two years of the announcement that there was a probable link between BSE and vCJD, an inquiry was set up to “*establish and review the history of the emergence and identification of BSE and new variant CJD in the United Kingdom*”.<sup>1642</sup> It started work just before Christmas 1997, and reported nearly three years later on 26 October 2000. Though reference should be made to the report itself for the full record of its findings and conclusions, some have particular resonance for this Inquiry. In particular, amongst these are the following:

- “• *The rigour with which policy measures were implemented for the protection of human health was affected by the belief of many prior to early 1996 that BSE was not a potential threat to human life.*
- *The Government was anxious to act in the best interests of human and animal health. To this end it sought and followed the advice of independent scientific experts – sometimes when decisions could have been reached more swiftly and satisfactorily within government.*
- ...
- *At times bureaucratic processes resulted in unacceptable delay in giving effect to policy.*
- ...
- *The Government did not lie to the public about BSE. It believed that the risks posed by BSE to humans were remote. The Government was preoccupied with preventing an alarmist over-reaction to BSE because it believed that the risk was remote. It is now clear that this campaign of reassurance was a mistake. When on 20 March 1996 the Government announced that BSE had probably been transmitted to humans, the public felt that they had been betrayed. Confidence in government pronouncements about risk was a further casualty of BSE.”<sup>1643</sup>*

In a section of its conclusions relating to communication of the risk posed by BSE to humans, the report added that:

*“The public was repeatedly reassured that it was safe to eat beef. Some statements failed to explain that the views expressed were subject to proper*

1641 House of Commons Science and Technology Committee *After the storm? UK blood safety and the risk of variant Creutzfeldt-Jakob Disease* 24 July 2014 pp34-37, pp41-42 TSTC0000052

1642 The Interim Response to the Report of the BSE Inquiry February 2001 p5 MHRA0021312

1643 The BSE Inquiry Report Volume 1 Findings and Conclusions 26 October 2000 pp1-2 CABO0000141\_004

*observance of the precautionary measures which had been introduced to protect human health against the possibility that BSE might be transmissible. These statements conveyed the message not merely that beef was safe but that BSE was not transmissible ... The impression thus given to the public that BSE was not transmissible to humans was a significant factor leading to the public feeling of betrayal when it was announced on 20 March 1996 that BSE was likely to have been transmitted to people.”*<sup>1644</sup>

## Financial support

On the same day that the report of the BSE Inquiry was published in October 2000, the Government announced, first, that it would set up a fund for the care of victims of vCJD to ensure a speedy response to diagnosis and improvement in the quality of care for such patients. The NCJDSU was to coordinate this. Second, it was to set up a compensation scheme to operate through a special trust fund.<sup>1645</sup> It was set up in April 2001 and interim payments of £25,000 would be made without delay on an ex gratia basis to families of those who had been diagnosed with vCJD.<sup>1646</sup> By October 2001, Alan Milburn, Secretary of State for Health, had announced further details of the compensation scheme. It was to be administered by an independent body, the vCJD Trust, and would provide payments of up to a maximum of £55 million for the first 250 cases with a discretionary fund capped at £5 million. The scheme would be updated if the number of cases exceeded 250. In addition, the Government was to pay an additional £50,000 to each victim or their family. This was to take account of legal and other difficulties the first families had had to encounter and the additional pressures they had had to bear.<sup>1647</sup>

If averaged out between the 250 expected cases this effectively provided for around £300,000 per family. The payment was not to be taken into account for the purposes of calculating income-related social security benefits nor be subject to “claw back” under the social security compensation recovery scheme.

## The vCJD Trust

The Trust has the following features of particular relevance to this Inquiry:

- (a) The chair of the Board of Trustees is, and has been throughout, a High Court Judge. Shortly after his appointment to the High Court Bench in 2001, Sir Robert Owen was invited to be chair of the Board of Trustees. Though he retired from the bench in 2014, he remains the chair of the Board. He believes that he was appointed because he had particular expertise in personal injury work, in particular having been involved in litigation concerning the effect of human growth hormone derived

1644 The BSE Inquiry Report Volume 1 Findings and Conclusions 26 October 2000 CABO0000141\_008

1645 Hansard extract on BSE Inquiry Report 26 October 2000 p2 MHRA0021233

1646 Briefing note on the vCJD No-fault Compensation Scheme 8 May 2001 p3 DHSC0004343\_029

1647 Department of Health Press Release *Compensation Scheme for Variant CJD Victims Announced* 1 October 2001 pp1-2 NHBT0008988

from pituitary glands harvested during post-mortem examinations, a number of recipients of which developed CJD at a young age.<sup>1648</sup>

- (b) He was consulted about the other six original appointments to the Board, which included two family trustees whose contribution to the work *“both in terms of their personal experience and as a channel of communication with the victims and their families, has been essential.”*<sup>1649</sup> It also included legal expertise from both north and south of the border. The trustees are paid on the standard scale applicable to non-departmental bodies appointed to advise the Secretary of State. There has been a continuity of trusteeship which in the view of Sir Robert *“has been of considerable benefit given the complexity of the Scheme and the reducing workload over the 20 years for which the Trust has been functioning.”*<sup>1650</sup>
- (c) Rather than have administrative staff, solicitors were and are engaged to undertake the necessary administrative work, as well as provide legal advice where needed.<sup>1651</sup>
- (d) The Trust uses the records they maintain of the claims made and determined to help ensure that decisions are consistent over time and with each other.<sup>1652</sup>
- (e) The Trust is under no obligation to report to the Department of Health; it is entirely independent of it. Its only involvement is where an amendment or variation is proposed to the terms of the Trust deed.<sup>1653</sup>
- (f) The NCJDRSU, to which a treating clinician is advised to report any suspected case of vCJD is required to ensure that the victim and/or his/her family are made aware of the vCJD Trust and the possibility of compensation. In effect, the NCJDRSU acts as a *“gatekeeper”*.<sup>1654</sup>
- (g) No claim is means-tested. A beneficiary’s circumstances and household income are not taken into account.<sup>1655</sup>

## Level of payments

There is a basic sum paid to all. In addition, there are payments made within a fixed range applicable to some heads of claim.

The basic sum as at May 2022 was £141,400 for victims diagnosed after 31 March 2021. It is uprated annually in line with the Consumer Prices Index.<sup>1656</sup>

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1648 Written Statement of Sir Robert Owen para 9 WITN6441001

1649 Written Statement of Sir Robert Owen para 11 WITN6441001

1650 Written Statement of Sir Robert Owen para 19 WITN6441001

1651 Written Statement of Sir Robert Owen para 18 WITN6441001

1652 Written Statement of Sir Robert Owen para 20 WITN6441001

1653 Written Statement of Sir Robert Owen para 24, para 26 WITN6441001

1654 Written Statement of Sir Robert Owen para 37, para 40 WITN6441001

1655 Written Statement of Sir Robert Owen para 47 WITN6441001

1656 Written Statement of Sir Robert Owen para 54 WITN6441001

As to some of the heads of claim, the trustees have fixed a level of £15,000 for those who have suffered particular emotional hardship; three levels of fixed award for those who have particular financial hardship (£10,000, £25,000 or £40,000); carers' loss of earnings at four levels (the same three as those relating to financial hardship, plus a lower, £5,000 level); and the same levels for victims' loss of earnings.<sup>1657</sup>

The original scheme contained a mix of fixed discretionary and ongoing claims, some of considerable complexity and thus costly to administer: Sir Robert's view a year after appointment was that the scheme the Trust was tasked to administer was a model of how a scheme ought not to be set up; he added, however, that it had been greatly improved by amendments since. Such was the complexity of the scheme that it had been costly to administer, a matter which has caused some concern to trustees. The views of Sir Robert expressed in his written statement are particularly valuable:

*“there are considerable benefits in operating such a scheme by means of a Trust. First and foremost the decision making has been informed by the involvement of Trustees of relevant expertise, and experience, in particular that of the family Trustees. Secondly, it gave the Trustees independence from the Government, which has been beneficial in terms of gaining the trust of the beneficiary community. Thirdly, and although some elements of the Scheme were unduly complex particularly in its pre 2010 form, the carefully defined provisions governing each head of compensation have ensured fair and consistent decisions over the years, and have kept disputes and complaints to a minimum. Finally ... The Trust Deed ultimately gave the Trustees the flexibility to make decisions on matters which had not been contemplated when the Deed was first drafted to ensure victims/families were adequately compensated and supported.”*<sup>1658</sup>

He went on to observe that when the initial 117 families negotiated the terms of the Trust deed they had successfully argued for several “discretionary awards”, payable based on the particular circumstances of the individuals claiming. He commented: *“In fact, it was these elements of the Scheme which proved most costly, time consuming and upsetting to family groups.”*<sup>1659</sup>

## Commentary

There is a dramatic, informative contrast between the way in which the transmission of both HIV and hepatitis were dealt with by clinicians, advisory and government bodies, and regulators and the way the risk of vCJD was handled.<sup>1660</sup> Did this lead to a difference in the

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1657 Written Statement of Sir Robert Owen para 58 WITN6441001

1658 Written Statement of Sir Robert Owen para 74 WITN6441001

1659 Written Statement of Sir Robert Owen para 77 WITN6441001

1660 This comment is made by way of comparison. It does not intend to suggest that the reaction to the risk of vCJD was a perfect model to follow – some evidence to the Inquiry suggests there would have been room for improvement: see, for example, the evidence of Professor Collinge, and that of Peter Buckland.

consequence? There has certainly been such a difference. The extent to which vCJD has been seen to occur as a result of the transfusion of blood or receipt of blood products is undoubtedly orders of magnitude less than in the cases of HIV and hepatitis.

However, there has to be a word of caution before accepting too easily that the difference in the approach to risk caused the difference in outcome – for obvious reasons, it has been impossible and unethical to conduct a study on people to establish what might have happened to them if the precautions had not been taken, compared with what did actually happen. This is one of the difficulties that any effective public health system will face. If it works as well as it might, the threats with which it deals will never seem to be real threats in the popular mind, but rather phantom menaces – for they will either not materialise at all or do so in a very limited number of cases. There may indeed be some “threats” which in time turn out to have been overstated. This in turn can lead to an absence of interest in financing and empowering a public health approach to many dangers – for those who in fact identify real dangers may be seen to be “crying wolf”, since the failure of previously imagined dangers to materialise (albeit as a result of successful precautionary measures) may suggest there are few real ones to overcome, and limit the will to resource public health adequately. The consequences of a failure to take enough measures, sufficiently strongly, sufficiently early, universally and sufficiently supported by the population, are clear when the failure materialises in disease and death, and will be the subject of complaint by many if they are not taken quickly. If however the system works, such that there is little or no disease and few if any deaths, then there is little complaint but a risk of much complacency.<sup>1661</sup> There is, however, much less disease.

### **The main similarities and contrasts in response**

Although some of the deficiencies in the approach taken initially to the risks of human beings being infected with vCJD as a result of eating beef were criticised by the BSE Inquiry as being reassuring rather than accurate and candid, and that trust in the authorities was sacrificed as a result, repeating the pattern seen in respect of HIV and hepatitis infections, in other respects there was a marked difference.

There are many points of similarity between HIV and vCJD as to transmissibility by plasma and plasma products. Both infections could not initially be detected before symptoms became apparent. Both had a long incubation period. Both had no cure: both could be fatal (though vCJD invariably so). Some of these similarities were shared with hepatitis, which initially could not be tested for, and manifested its worst effects after a long incubation period. There was treatment, however, available for Hepatitis C in due course, though the treatment brought its own problems as described elsewhere in this Report.

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<sup>1661</sup> The House of Commons Science and Technology Committee appears to have thought this had happened with the continuing response to vCJD – it regarded the NHS as resistant to change. See its report in 2014: House of Commons Science and Technology Committee *After the Storm? UK blood safety and the risk of variant Creutzfeldt-Jakob Disease* 24 July 2014 p25 TSTC0000052



However, there were two important differences between vCJD on the one hand, and HIV and hepatitis on the other. Firstly, those suffering from vCJD did not have to suffer stigma of the nature endured by those with HIV in particular, but also by many with Hepatitis C; and, secondly, they did not have to wait so long for substantial financial support to be given, or for that matter for an Inquiry to be set up.

Other differences highlight the inadequacies of the response in particular to HIV infection. In the case of vCJD significant precautionary and protective steps were taken to prevent transmission through blood and blood products. Thus blood donations from those who might pose a risk were declined even whilst the risk remained purely theoretical. Expensive steps were taken to ensure the leucodepletion of blood. UK-sourced plasma ceased to be used as a basis for blood products. The Government went so far as to purchase a US plasma collector to ensure a continued supply of plasma which was likely to be free of the problem prion, and did so before there was a single known case, anywhere in the world, of the infection being transmitted by blood. The principle of “no evidence of harm is not evidence of no harm” was in effect applied<sup>1662</sup> in respect of vCJD, at least after 2006, so far as recipients of blood and plasma products were concerned.

By contrast, in the case of AIDS, Professor Arthur Bloom appeared to suggest to the public that the (cause of the) disease was not transmissible by blood, and pointed out that there had been no case of it in the UK as a reason for inaction – though there had been a number of such cases in the US. When one case of vCJD arose which was probably caused by transfusion, it spawned further protective measures, all designed to minimise the risk as far as possible. By contrast, very little happened to prevent the further transmission of a probable cause of AIDS by transfusion once it became known that there were one or two cases of infection in the UK in 1983 from that route,<sup>1663</sup> and (worse still) after the first reported death of AIDS in a victim almost certainly infected through blood products. Whereas the taking of precautions, in particular probably leucodepletion, may well have prevented significant numbers being infected with vCJD through transfusion or the receipt of blood products, the failure to take precautions against the risk that HIV was transmitted by blood, as described elsewhere in this Report, contributed to the significant number of deaths and serious infections with HIV in the UK.

There are also comparisons to be made in respect of the financial response of the government towards those who suffered the infections. Both the scheme for vCJD and the schemes for HIV and Hepatitis C were expressly *ex gratia*. But the sums awarded to the Trust to be paid to the families of vCJD victims dwarf the sums paid to those suffering from HIV and Hepatitis C. Moreover, an express component of the payments made to the families of initial victims of vCJD was made to reflect the struggles they had to find the disease recognised as a consequence of animal food policy. By contrast, those who were infected with either

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1662 No one described the principle in these terms, but it makes for a pithy summary of part of the basis on which the approach taken was adopted.

1663 To administer blood products is in essence the same process as to transfuse blood – the characteristics of one person’s blood are transferred to the circulation of another with a view to the restoration of their health.

or both HIV and Hepatitis C had a long struggle for recognition of the moral case they had for financial support, and through much of that period had to contend with the corrosive effects of stigma on most aspects of their daily lives. When, eventually, the Alliance House organisations and special payment trusts were used as a vehicle to pay some sums in support to victims of blood-borne HIV and Hepatitis C, those trusts and schemes lacked the advantageous features of the vCJD scheme identified above. Though Sir Robert was concerned about the complexity of many of the provisions governing the Trust, in other respects it was a model solution compared to the trusts and schemes described in the chapters on the Alliance House organisations.<sup>1664</sup>

In both the cases of vCJD on the one hand, and HIV and Hepatitis C on the other, there was a misplaced reluctance to tell people that they might be particularly at risk of infection for fear that it might cause panic or in some way affect future donations to the blood system. The views described above of Professor Sir Ian Kennedy and Professor Doyal in respect of telling people they were at a raised risk of vCJD were appropriate. People should have been told. The reluctance to operate on the basis that individuals were at a raised risk of vCJD resonates with the desire in the early days of the government handling of the potential spread of AIDS through blood and blood products to reassure the public.

The communication of risk to the public, to the extent many felt betrayed, drew particular criticism from the BSE Inquiry. It is a further tragedy that the lessons of the handling of communicating the risks of HIV/AIDS appear not to have been learned by the time of the BSE Inquiry. However, perhaps the bigger tragedy still is that in the face of unknown diseases which were potentially transmissible by blood the government was able in the 1990s and early 2000s to demonstrate that taking a proactive, precautionary approach could avert much disease – it will have left many people infected and affected by Hepatitis C or HIV both disappointed and angry that such an approach could not have been taken in response to earlier blood-borne infections.

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1664 See the chapters on the *Macfarlane Trust*, *Eileen Trust*, *Skipton Fund* and *Caxton Foundation*.

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