Witness Name: Dr. Huw Lloyd

Statement No.: WITN6935001

Exhibits: WITN6935002-35

Dated: 8 January 2022

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR. HUW LLOYD

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 2 June 2021.

I, Dr. Huw Lloyd, will say as follows: -

Section 1: Introduction

1. Personal Details

Name: Huw L. Lloyd

Address: GRO-C Ontario, Canada

DOB: GRO-C 1949

Qualifications:

M.B., B.S. (Royal Free Hospital School of Medicine/University of London)	1974
MRC Path. (Haematology)	1986
Accreditation from the Joint Committee on Higher Medical Training	1986
Fellow of the Royal College of Pathologists (FRCPath.)	1995

Other:

Honorary Clinical Lecturer, University of Newcastle upon Tyne	1988-1995
Examiner for Royal College of Pathologists	1991-1995

2. Employment History

House Officer (Medicine) Kings Lynn & West Norfolk General Hospital	1975
House Officer (Surgery) North Tees General Hospital (NTGH)	1975
Senior House Officer (Medicine) Rotation through medical units at NTGH including periods in Intensive Care Unit and Cardiac Intensive Care Unit, Combined medical & surgical unit for gastro-intestinal diseases (NTGH), Medical unit North Ormesby General Hospital and Neurology unit Middlesbrough General Hospital	1976-1978

Senior House Officer (Neurology) Newcastle General Hospital	1978-1979
The above were standard House Officer/SHO appointments, with no special emphasis on haematology or blood transfusion.	
Locum Registrar (Blood Transfusion) Northern Region Blood Transfusion Service The work involved reviewing donor information collected by clerical staff at collection sessions, and assessing if the subsequent donation was fit for use based on the current standards, assessing demand for platelet concentrates and allocating collection quotas for upcoming sessions and reviewing temperature records from session transport vehicles. I also spent time in each of the departments of the centre including the blood banking operations, component production, infectious disease testing, donor panel (the clerical operation responsible for planning donor sessions, recruiting new donors and inviting donors to the sessions). Latterly I was part of a three-person team tasked with introducing automated blood grouping, replacing the then manual processes. The introduction of the automated system resulted in the almost complete elimination of incorrectly labelled (ABO/Rh) units of blood.	1980-1981
Registrar (Blood Transfusion and Haematology) Newcastle AHA(Teaching) This position provided training and experience in all the main disciplines in pathology. The post included periods in the	1981-1983

haematology, chemical pathology, microbiology and histopathology departments at Freeman Road Hospital, as well as secondment to the Public Health Laboratory. There was also a period of time spent back in the Northern Region Blood Transfusion Centre. The haematology department provided insight into hospital blood banking, the use of blood products and clinical issues resulting from transfusion. In the Transfusion Centre, I covered much of the same responsibilities as in the Locum Registrar position, as well as becoming familiar with the availability of the rarer blood groups. Further work was carried out on the automation of blood bag labelling and the start of a computer program to handle the recording of blood component production. Towards the end of this appointment I was successful in the part 1 MRCPath examination.	
Senior Registrar (Blood Transfusion and Haematology) Northern Region Health Authority This position involved periods in each of the three main teaching hospitals in Newcastle, a period working in the Regional Haemophilia Centre and a further period in the Transfusion Centre. As expected in a Senior Registrar position there was much more emphasis on the clinical care of patients with haematological disorders. In-patient care was provided and out-patient care was provided at regular clinics. Regular on-call work was included. Newcastle General Hospital covered a wide range of haematological disorders, excluding acute leukaemia, Freeman Hospital had a similar wide range as well as a substantial blood banking operation supporting cardiac surgery. The Royal Victoria	1983-1987

Infirmary (RVI) provided the acute leukaemia care including an active bone marrow transplant program both allo- and auto-transplants. I was actively involved in the care of patients with acute leukaemias including those undergoing transplants. Whilst at the RVI I spent time in the paediatric haematology unit, as well as the Haemophilia Centre. At the RVI, out of hours care for haemophiliacs was provided through the haematology unit. During this time I was successful in the final MRCPath. haematology examination. Working at the Transfusion Centre I took on more responsibility for the provision of platelet concentrates, providing clinical advice to hospitals, and answering issues brought up by donors.	
Locum Consultant Haematologist (Northern Region Blood Transfusion Centre) This position was technically a secondment from the Senior Registrar position. The answer in 2.8 provides details of the role.	1987
Consultant Haematologist (Northern Regional Blood Transfusion Centre) In the period between appointment and becoming Medical Director I continued in a similar role to that outlined for the locum position, although I became more involved with management issues.	June 1987 – October 1988

Medical Director/Chief Executive (Northern Region Blood Transfusion Centre) In 1998 the Northern RHA made an administrative decision to offer me this position, with the then Director moving to the clinical Haematologist role. Although my focus changed to the management and development of the service, I retained clinical responsibilities and participated in the on-call rota.	November 1988 – February 1995

3. Memberships

Member of the British Blood Transfusion Society

Start date not known, member until 1995.

4. Ongoing Education

As part of the Northern Region haematologists group I attended the regular weekly meetings which kept me up to date on current clinical issues, including changes in treatment protocols for example in acute leukaemia. Short topic presentations also took place spotlighting issues of interest and some sessions included 'interesting' journal articles. I did not attend every week but certainly on a regular basis over the years. I first attended these meetings when I was in the locum Registrar position.

I attended the annual BBTS conferences which had lectures covering a wide range of Transfusion topics.

The Northern Region Transfusion Centre had a library and a good range of journals were subscribed to, covering blood transfusion, haematology and tissue typing. As Director and then Chief Executive I was able to have the contents pages of selected journals photocopied, and I would then select

articles that I wished to read. These were photocopied for me, and after review, I filed selected articles for later reference.

I also wrote review documents for internal use, for the Centre's business plans and presentations for meetings which required up to date literature. For example in October 1992 I prepared notes for a presentation I was giving about risks associated with Transfusion and alternative strategies. (I do not recall the meeting that I prepared this for). A scanned copy of the document 'Transfusion – Do We Have Any Choice', WITN6935018 is attached.

5. Possible Involvement in Litigation Related to HIV or HCV.

5(a) TYWE0000067 – I have read the attached document and it was prepared by me. The content is to my reading of it now, appropriate and to the best of my recollection, accurate. Apart from preparing this document, I had no further involvement with the litigation.

5(b) TYWE0000064 – I have read the attached document and it was prepared by me. The content is to my reading of it now, appropriate and to the best of my recollection, accurate. Note: The abbreviation BTC refers to Blood Transfusion Centre, and in context refers to the Newcastle Centre. As noted above, I had no further involvement with the litigation, apart from the formal statement shown in TYWE0000067

5(c) NHBT0034961_137 - Regarding the solicitors referred to in this letter, I do not recall receiving further contact from them, and to the best of my recollection. I was not asked to provide a statement.

6. Documents

I have read document TYWE0000067. The attachment, although not signed, was prepared by me. The 'With Compliments' slip attached to the document has a handwritten note which is not in my writing. Despite this the

corrections appear appropriate and look to have been made by me. The content of the document is to my reading of it now, appropriate and to the best of my recollection, accurate.

7. Further involvement

I have not been involved in any other inquiries etc.

Section 2: My role at the Newcastle Regional Transfusion Centre

8. Roles by appointment

8(a) Senior Registrar

This was a training position and I was not involved in policy decisions. I provided clinical advice and handled issues such as the provision of blood products including platelets.

8(b) Locum Consultant Haematologist/Consultant Haematologist

This position involved becoming the primary interface between the haematologists in the Northern Region and the Transfusion Centre. This involved managing inventory, particularly platelet concentrates and other inventory at times of shortage of specific products or blood types. General management support was provided at a time of some instability in the running of the Centre. I was also involved in providing clinical advice associated with the Centre providing ante-natal serology services to the maternity hospital in Newcastle. I provided support to Clinical Assistants looking after post-donation information from donors and information collected by clerical staff at blood donor sessions.

8(c) Medical Director

The role of Medical Director and General Manager primarily provided the management direction for the Centre and with the approval of the

Northern Regional Health Authority, changes in the way that the Centre operated. As Medical Director I was responsible for the overall care of donors, the standards for donor eligibility and how they were applied. I continued to provide advice to hospitals and continued on-call duties.

8(d) Chief Executive

This change initially made little difference to my roles, until the appointment of a Clinical Director which allowed me to spend more time on the direction that the centre would take, the development of quality systems, and computerization.

The financial management also became more important with the devolvement of financial systems from the Northern RHA to the centre and later, the change in funding arrangements with hospitals being funded to obtain the blood and blood products they required and contractual arrangements being put in place.

I continued to develop statistical reports at a management level to help guide the operation, with clear targets, data on progress 'to date', comparison with previous year data, and key features such as the number of usable donations prepared compared to the number of donors attending.

In my last year in this position I was frequently involved with discussions and planning associated with the upcoming transfer of all the Centres in England and Wales from Regional Health Authority responsibility to the new National Blood Authority (NBA).

9. Reorganization

A wide range of changes were introduced during this time. A new management team was developed with a focus on helping departments work together. The laboratory operations were reorganized with an emphasis on

the skill sets required rather than the traditional functions, for example, the main blood banking and ante-natal serology departments were merged, to make better use of available automation. This also brought all laboratory operations under one manager. The ordering and delivery of blood and blood products was overhauled with an aim of providing the service that each hospital required, rather than one focused on the Transfusion Centre's convenience.

The testing of donations for infectious diseases was consolidated using a single manufacturer's system. Although on a test by test basis this was more expensive, it brought numerous improvements such as a simple computer-driven release authorization for batches of tested donations, complete interoperability for staff between different tests and a reduction in the training requirements – one system instead of several. It also laid the ground for an easy introduction of hepatitis C testing.

A new quality assurance department was created with the QA manager independent of the laboratory management, with a direct route to the Chief Executive.

Blood donor services were also changed with an attempt to ensure that donors were informed about donation criteria before attending, the aim being to reduce wasted time for donors who turned out to be ineligible. As with many other aspects of the Centre's operation, regular statistical reports were produced to help track the changes and to help direct future changes. For the donation 'system' the aim was to ensure as far as was possible, any donation made would be fully usable. In the past many donations were labelled for 'laboratory use' because of limitations in the donation process. New documentation was produced to support the clerical staff at the donor sessions, particularly to provide clear information on medication taken by donors prior to donation (developed with the University of Newcastle, Wolfson Unit), and precise and complete information on travel-related restrictions to every country.

Computerization of many parts of the system were introduced during this time. In April 1991 the Blood Management Computer Network System (BMCNS) was introduced. This was the last in-house developed computer program. It covered all component production work, the testing of all donations, the associated clerical work and medical information and the verification, labelling and dispatch of all units of blood and blood components. It recorded all donations made, registering information about the blood packs, their type and their Lot or Batch Numbers. The program was written by Mr. Brittain, a member of the laboratory staff and who later became the Centre's IT manager.

In the 1993/94 business plan, see 'Computerization Summary 1993-94.pdf, (WITN6935019), I noted that:

> … the BMCNS will ensure that another area of our operations meet GMP Guidelines and meet the requirements of the Medicines Inspectorate'. Among other benefits it allowed the Centre to rapidly identify the location or disposition of any donation and its products that needed to be withdrawn due to post-donation information. A process that had taken sometimes days, and always hours was now completed in minutes.

Later the Blood Donor Management System (BDMS), a donor module from the US company that had written the laboratory system for Abbott was introduced. This module provided the core of a Transfusion Centre-wide system and although providing the systems for Donor call-up and Donor registration it also held all the test data and clerical and medical clearances.

The last module to be introduced was the CDIC, a components management module, also written by the same company. When the donor module went live, it allowed the Centre to archive the half a million or so 101 file cards that had been in use for decades, and to retire the 1980 ICL computer.

At my request, the Birmingham University Health Services Management Group carried out an assessment of the management of the Centre and

developed a program of management development. This program started with the senior managers, myself included, and later management development was extended to departmental managers and supervisors.

A wide-ranging quality systems program was developed. Amongst many other things, it was part of the process that led to the Centre's accreditation to BS 5750 part 2 (later ISO 9002). As far as I know, this was the first Centre worldwide to achieve this standard.

The Center's quality assurance program was also extended.

During this time it was recognized that more attention needed to be given to the 'Transfusion Medicine' part of the Centre's role and a new Clinical Director post was created with the appointee part of the management team.

On a slightly different track, I was aware of the poor performance of the Centre in producing plasma for processing at the Elstree Blood Products Laboratory. There were several reasons for this, but the prime reason was rooted in the laboratory operations that I had seen when I first worked in the Centre in 1980.

At that time it was a mantra that whole blood supply was the priority, albeit tempered by the need for the preparation of platelet concentrates. Staff in the component preparation department were often underutilized as blood destined for plasma/concentrated cells was retained as whole blood.

To address this issue an initial meeting was organized for haematologists from all the hospitals supplied by Newcastle, to discuss the issue. Data on whole blood and component use was provided. Newcastle was, I think, in the unique position that all unused blood and components were returned to the centre. This showed that most of the returned, outdated blood was indeed whole blood and not concentrated cells.

As a result of this meeting an initial target for the percentage of whole blood to be made available was accepted and was duly implemented. The only

hospital that complained was one that had not been present at the meeting. A further meeting to follow up on issues and to review progress agreed to a further reduction.

In the 1985/86 year over 62% of all red cell products prepared were whole blood (over 76,000 units). As shown in the chart 'Percentage of Red Cells Issued as Whole Blood 1985/86 to 1993/94' (WITN6935002), by 1992/93 the percentage was less than 1% and only 0.16% (203 units) in 1993/94. The amount of plasma sent to BPL increased from 8.5 tonnes in 1985/86 tonnes to 33.9 tonnes in 1993/94 as shown in the chart 'Plasma Dispatched to BPL 1985/86 to 1993/94' (WITN6935003). The apparent fall in plasma in 1993/94 is due to variations in dispatched volumes, with 1992/93 likely being a year in which an excess of plasma in store was shipped to BPL. I have a record of production, as opposed to dispatch for the last three years shown, as seen in the table 'Plasma Produced 1991/92 to 1993/94' (WITN6935004) which shows a simple year on year increase, with 1993/94 being the highest with production of just over 35 tonnes.

I must thank the haematologists and blood bank staff in the hospitals supplied by the Centre for making this possible.

The new Operations Manager position was aimed at continuing to develop a single focus on delivering the blood and products that the hospitals required. This was part of a continuum of change from a period before I was Medical Director where each of the main departments operated more or less based on their departmental needs rather than for the overall need.

The Operations Manager was also in a position to manage new developments such as the complete overhaul of the blood component manufacturing facility and the introduction of white cell reduction technology.

The appointment of a Consultant Haematologist as the Clinical Director was another important change, providing better direct access between the Centre and hospitals in the Region. It also allowed for new input into an autologous

transfusion pilot program and a new bone banking operation, both of which required considerable dialog with other clinicians.

10. Organization

10(a) As Medical Director/General Manager, I was responsible to the Chief Medical Officer of the Regional Health Authority. In practice this was usually delegated. At first my point of contact was the Regional Scientific Officer, but this changed to one of the RHA's Directors. If I recall correctly, that position held responsibility for not only the Transfusion Service, but also the Ambulance Service and a number of clinical support services run at Regional level.

The amount of input from the RHA declined considerably after my first year or two. Bi-annual reports on performance were prepared and duly discussed, and specific issues were discussed as required.

I think that it was as a result of the 1990 National Health Service and Community Care Act, that the RHA moved the Transfusion Service into an arms-length organization, that it referred to as a Clinical Agency of the Regional Health Authority. This changed the management arrangements leaving the Centre's management team with more authority for the running of the Centre.

As mentioned in TYWE0000067, there was an Administrator position in existence when I started. My understanding was that this position had been created and filled at the insistence of the RHA during my predecessor's tenure, to address some of the management issues at the centre. The individual had been given direct access to the RHA, by-passing the Medical Director, a highly unusual arrangement. I quickly became aware of how this arrangement was proving divisive amongst senior staff and was not conducive to good management. I removed this position shortly after becoming the Director.

With the implementation of weekly management meetings, the heads of each of the main departments; Medical (a Consultant Haematologist), Nursing, Donor Services, Laboratories, Administration and Quality Assurance attended. Later the new Medical Director attended and also the Finance manager. Minutes of meetings were prepared and circulated to all attendees.

10(b) For most of the time funding, both operational expenditure and capital, was provided directly from the RHA, based on a yearly submission from the Centre. There was usually considerable discussion over capital requirements.

The RHA was generally opposed to funding new staff positions. I later was told that this arose from my predecessor's decision to not reduce laboratory staffing levels following the introduction of automated blood grouping.

During my time as Medial Director and later Chief Executive, this was not an issue as the implementation of computerization and various reorganizations resulted in a reduction in total staffing.

The impact of the change in funding from a direct RHA allocation to hospital budget purchasing did not have a significant effect during the time I was in post.

10(c) The Northern Region Blood Transfusion Service collected blood from donors and distributed blood and components to an area approximating that of the Northern Regional Health Authority. The minor differences were due to geography, with Northallerton included to the south-east of the RHA region and an area of Cumbria to the south-west of the RHA region, around Barrow-in-Furness, excluded. One hospital just north of the Scottish border, near Carlisle was also

supplied, but I do not recall that any blood donor sessions were held in this area.

The population covered was approximately 3.1 million.

10(d) The statement by Dr. H. H. Gunson, paras. 4-16 in document NHBT0000025_001 refers in large part to a period before I became Director. The overall relationship vis-à-vis the Nation Directorate was already in place.

Note: The document as provided is missing page #3, so paras. 4 to 6 were not available.

I note the following extract from this document:

> It is important to stress that the National Directorate did not have any executive authority and its successes came about by persuasion. The RTCs remained the primary responsibility of the RHAs. There were inevitably difficulties when proposals from the National Directorate for a change in national policy required additional resources, since these had to be found from the budgets of the various RHAs.

I understand that there were difficulties with funding new proposals put forward by the National Directorate, and a lack of executive authority to implement them. However the National Directorate was not structured or staffed to take on this role and should have concentrated on getting agreement amongst Centre Directors on issues of major importance, and once agreed could have helped individual Centres who experienced problems as a result of their RHA's role, through its direct access to the Department of Health.

Despite the National Directorate's non-executive position vis-à-vis the RTC's, it is of note that all Centres initially accepted a decision to only implement HCV testing when the National Directorate gave the green light. The Centres, with the exception of Newcastle, held to

this decision even when the implementation date was delayed further because some Centres were still not ready to start.

The split of the National Directorate's meetings of Centre Directors/Chief Executives into divisional meetings did not support the concept of obtaining agreement across Centres to implement national policies.

The document NHBT0000026_009 has the following sections:

A The organisation of the NBTS (1946-1993)

B The hepatitis C virus and its discovery

C Surrogate testing for hepatitis NANB .

D The introduction of anti-HCV tests

and three appendices of which #1 is relevant:

Appendix I Dates of introduction of anti-HCV screening

The question posed relates to organization of the Centres and their relationships, and as such no comment is made here on the implementation of HCV testing.

There is this statement shown in the referenced document, item 7 (section A):

> It is important to appreciate that each RTC was managed by its own independent medically-qualified Regional Transfusion Director (RTD), appointed by and answerable to his or her Region and concerned to meet the needs of that Region. The Regions were of course geographically and demographically diverse, and RHAs inevitably varied in their funding policies and priorities. Thus matters of policy relating to collection of blood within the Regions, and arrangements for the management and operation of the RTC came to vary substantially over the years.

I cannot comment on the fact that Dr. Gunson believed that arrangements for the management and operation of the RTC came to vary substantially over the years, as I did not have any detailed knowledge of the organization of other Centres. However at a high level, it appeared that all Centres were attempting to provide the same service, albeit with relatively minor differences where some Centres provided other services, such as ante-natal blood testing histocompatibility/transplant services and frozen blood banking.

Perhaps of note were Centres that consistently required imports of blood, suggesting a failure of adequate funding or adequate management.

This statement in item 9 (section A):

> There was no central organisation to ensure that those functions which were common to all RTCs operated in a uniform manner.

... was being addressed by the implementation of audits of Transfusion Centre's operations by the MCA particularly after the removal of Crown Immunity. This and changes in liability legislation moved standards closer together.

For example the Newcastle Centre made changes as a result of the MCA audits, changing the timing of a second phase of the Transfusion Centre's computer system to meet requirements put forward by the MCA's inspector.

Sections B, C & D and Appendix I do not substantially address the position of the Regional Centre within the NBTS framework.

As to the question:

> ... information as to whom the RTC was answerable to at the NBTS, if anyone.

I was clear that line of management and accountability was to the Regional Health Authority.

Regarding the NBTS, I have assumed this to mean the National Directorate as this had taken over from an Advisory Committee prior to my appointment as Director. From my perspective as a newly appointed Director and having had conversations with my predecessor Dr. Anne Collins, I felt clearly that I was answerable to Dr. Gunson at the National Directorate in as much that I would not have considered refusing to respond to issues bought up by him. On the other hand I would not have taken actions that he requested if I felt that they required approval by the RHA, required additional funding, or were not in the best interests of patients, donors or the service we provided to hospitals.

Regarding Dr. Gunson's comments in NHBT0000025_001, I note that page 3 is missing, and this page is part of his comments on the organization of the NBTS (1946-1993). However the missing period is covered in NHBT0000026_009. I note that Dr. Gunson states: 'It is important to stress that the National Directorate did not have any executive authority …'. This appears to be a constant theme, and is in my view correct.

10(e) Association and Links with other Regional Transfusion Centres.

There were no formal links with any other Centre, however there were no barriers to contacting other Centres and I cannot recall any incidences when contact was rebuffed or help refused. Nevertheless the introduction of Hepatitis C testing created considerable strains, particularly with the SNBTS.

10(f) Regulation.

The Centre was subject to the regulations of the MCA as they pertained to the manufacture of blood / blood components. Audits show that this regulation covered a broad swath of the Centre's operations from transport vehicles to the details of infectious disease testing. It did not cover the clinical operations such as ante-natal testing or tissue typing.

There were other regulations, usually specific to a certain segment of the operations that became active once Crown Immunity was removed. Fire regulations for example required the Centre, (which was newly constructed in 1985) to implement additional fire precautions including new fire-stop doors, and a new emergency building exit.

The loss of Crown Immunity also meant that Transfusion Centres would need to hold manufacturing licenses equivalent to those held by pharmaceutical manufacturers and MCA audit findings would no longer be 'advisory'.

10(g) Relationship with the Blood Products Laboratory (BPL)

Initially I had little communication with BPL as it was then known.

We provided plasma and we received processed products such as factor VIII. I had no input into the quantity of products we were allocated. It was only after some management changes at BPL that communication increased.

10(h) Relationship with pharmaceutical companies involved in the production of blood products.

We did not have a relationship with any company involved in this business. We did have a relationship with divisions of multi-national

corporations for non-blood product items such as Baxter for blood packs and Abbott for test kits.

The Centre had no part in the purchase of commercial coagulation products, with the Newcastle Haemophilia Centre dealing either directly or through its hospital pharmacy for purchase and supply. None of these products came through the Newcastle Centre.

10(i) Donations collected annually

In 1985/86 132,670 donations were made by blood donors in the area served by the Centre. By 1993/94 the number of donations collected had risen to 142,690 of which 12,597 were new donors.

The annual changes over this period can be seen in the chart 'Donors Bled Per Year 1985/86 to 1993/94', (WITN6935005).

The change in the number of donors over a much longer time period can be seen in the chart 'Donors Bled 1947 to 1994', (WITN6935006) and the table 'New Donors Attending & Bled 1985/86 to 1993/94', (WITN6935007) shows the new donor numbers.

11. Self-Managing Trust

The document referenced in the question only contains the following that is relevant to the question:

'The Newcastle expression of interest in opting out had been put on ice'.

which was recorded in 'Informal Notes of the Meeting of the Northern Division of the NBTS held on 19th October 1989' (SBTS0000096_076) and included the above comment under a note headed:

Points from the Minutes of the NBTS Management Committee Meeting of 24th August 1989.

The application to become a self-managing trust came at a time when there was still a lot of detailed 'input' from the RHA which did not add a lot to the management and development of the Centre. A self-managing trust seemed to provide an opportunity to make changes and improvements to the operation of the Centre in a timely manner.

The RHA's direct involvement in the running of the Centre had already started to decline, then, I think that it was as a result of the 1990 National Health Service and Community Care Act, the RHA moved the Transfusion Service into an arms-length organization, that it referred to as a Clinical Agency of the Regional Health Authority. This changed the management arrangements and the Centre was able to change and improve more freely within the new organizational structure.

12. Clinical, Service and Business Plan for the Newcastle RTC for 1992-1993

In my forward to that year's business plan, I stated:

> '... it is important that the NRBTS provides the service demanded by its three groups of 'customers' - Patients, Hospital Blood Banks, and of course blood donors.

I think that this statement is clear and does not require further comment.

I authored the Plan and as a management team we were committed to improvement and delivering what our customers required.

Section 3: My role at the Newcastle Haemophilia Centre

13. Appointment at the Haemophilia Centre

I did not hold an 'appointment' at the Newcastle Haemophilia Centre.

Document TYWE0000067 does not indicate that I held such an appointment.

As part of the training of Senior Registrars in haematology there was an assignment to the Haemophilia Centre for a few weeks. I do not recall the actual duration.

14. Roles, functions and responsibilities

As this was a short assignment during training, I did not participate in any decision making on the source of medication used by individual patients. I would see some patients with bleeding disorders, the patients having fairly free access to the Centre and sometimes ordered treatment which was then administered by staff in the Centre. For those patients requiring a coagulation factor concentrate, the product to be used was already assigned. I also attended clinics with the Director, Dr. Peter Jones and participated in patient assessment. Some patients exhibited symptoms associated with HIV infection.

15. Staff and Relationships

Apart from the Director, Dr. Peter Jones, there was a nursing Sister in the Centre and a small number of other nursing staff. I was not in the Centre long enough to comment on 'relationships'.

Section 4: Blood collection at the Newcastle RTC

16. System of Blood Collection

Blood collection took place at sessions organized by the Centre's Donor Services department.

The sessions had historically been classified as 'general public' or 'industrial'.

Industrial sessions took place at factories and the like, with the establishments support, help in organizing and providing time away from

work for the members of staff to donate. These industrial sessions were nearly all during the 'normal' working day, that is between 9am and 5pm.

There were, to my knowledge, no incentives to donate, with the exception of sessions at prisons (see answer 18 below).

The number of donors from industrial sessions declined with the loss of heavy industry, particularly in the north-east of England.

As reported in the Centre's Clinical Service and Business Plan 1991-92 there had been a massive loss of donors, particularly from the industrial sector over the previous decade. The change in the five years between 1979 and 1985 is shown in 'Donors & Place of Work Post 1979', (WITN6935008).

The chart 'Industrial Donations as Percentage of All Donors Bled & Unemployment Rate', (WITN6935009) shows the decline in the percentage of donations that came from industrial sessions over the following period from 1985/86 to 1993/94. Despite the unemployment rate improving, there was no return of the heavy industry that had supported the 'industrial' donor sessions.

The general public sessions mainly took place in church halls and community centres. These sessions were held in the afternoon and early evening, typically between 3pm and 7pm.

On weekdays five sessions were held each day with a further two on Sundays.

After the opening of a new Transfusion Centre in Newcastle, a few sessions were held in the Centre itself, some on Saturday's. Over holiday weekends some small, targeted sessions were held specifically for collecting donations for the preparation of platelet concentrates.

17. Collection System Details

17(a) Staffing arrangements

Staffing varied according to the type of session and expected number of donors.

The general structure when I started included two clerical staff from the Donor Services department, a session manager, either an individual promoted from donor attendant or a qualified enrolled nurse recruited directly for the role. A number of donor attendants made up the bulk of the staff. A medically qualified doctor was present whilst the session was operational and undertook the venepunctures. One member of the laboratory staff undertook the haemoglobin testing. There were two drivers, one to drive the equipment/blood storage vehicle and the other to drive a bus transporting staff.

See subsection 17(e) below, for changes during my tenure.

17(b) Where did these sessions take place

See 16 above.

17(c) How frequently could a person donate blood

The aim in the Centre was to maintain donation frequency at a maximum of once per six months. This was generally less frequent than was considered acceptable, thus allowing

- flexibility on the dates at which the same session with its associated donors could be held and
- earlier invitations to donate could be made if demand required it.

The leaflet sent out with invitations to donate, around 1989/1990, as shown in 'Donor Information Leaflet 1989_90', (WITN6935020) included this:

Frequency of Donation

Donors are invited to give blood at intervals of not less than 5 months.

Donors may however give blood after an interval of 17 weeks (about 4 months), so if you see a session advertised that you would like to attend and it is 17 weeks or over since your last donation you will be very welcome.

17(d) How were blood donors recruited

Industrial session donors were recruited by the senior staff in the Donor Services department approaching the management of factories, major industries and large clerical establishments. Donor recruitment within those organizations was then undertaken in conjunction with the local management.

General public sessions had typically been operating for many years and specific recruitment drives started if the number of donors attending had fallen.

There was a general on-going recruitment through advertising in local newspapers, some of the local papers, if I recall correctly, provided free advertising.

The Centre had a publicity trailer which was taken out to local towns usually during locally organized events. This provided a substantial visual focus for recruitment and the unit was staffed with individuals who were knowledgeable about the donation process and eligibility criteria.

See 17(e) below for some other initiatives and changes.

17(e) Did any of these matters alter during your tenure

The massive decline in industry in the region resulted in more emphasis on general public sessions. As shown in 'Donors & Place

of Work Post 1979' (WITN6935008), in 1979/80 approximately 52,000 donations came from 'industrial' sessions, falling to a nadir of just over 35,000 by 1988/89 as shown in 'Industrial Donations 1985/86 to 1993/94', (WITN6935010). The unemployment rate in the North of England had reached around 18% in 1984, falling slowly after that year. There was no recovery in the heavy engineering sector, including shipbuilding which had provided many large and easy to run blood donor sessions.

Apart from the need to increase general public sessions, the change shifted the timing of blood collection, which in turn affected the processing of the blood with an increase in evening working. The change also altered the requirements for driving staff. The Centre had operated a fixed quota two-shift system for drivers, one 'early shift' and one 'late shift'. With the move to more afternoon/evening sessions this fixed quota of staff led to increasing inefficiencies within the transport operation.

This led to a review of transport requirements and transport staff skills. At blood donor sessions, once the equipment was unloaded and setup the two drivers had virtually no work until the end of the session, apart from moving full crates of donations out to the refrigerated compartment of the equipment vehicle.

Despite considerable opposition from unionized staff, a new driving/donor attendant position was created. This allowed the driving staff to be trained for and subsequently participate in donor care during the sessions. All the staff involved were newly recruited for these positions.

The use of laboratory staff for haemoglobin testing was also phased out and donor attendants were trained to perform this task. Again

there was considerable opposition to this change from the unionized staff.

These changes increased the flexibility of staffing on sessions.

The geography of the region affected blood collection because of the poor road connections to Cumbria in the west of the region. This had resulted in teams for these sessions being dispatched the day before the session and being accommodated in local hotels overnight, sometimes being away for three days in a row. A side-effect of this was that fewer sessions were carried out in this part of the region than its population would warrant.

Eventually a new team was recruited in Cumbria with a small facility in Cockermouth rented for use as a base for the manager, and equipment storage. All the new staff lived in the area.

18. Collections of blood from prisons, borstals and similar institutions.

During my tenure blood was not collected from these institutions.

My predecessor, Dr. Anne Collins, had noted that the rate of Hepatitis B positivity was higher in prison donor populations and as a result she recognized them as higher risk and stopped all of these sessions.

I am not sure of the date when she implemented this change, although I think that these sessions had been discontinued by 1981.

In NHBT0008628_001 which records a 'Telephoned survey of England and Wales Transfusion Centres regarding use of prisons as a source of donor blood.', dated 1983, I note the following:

> NEWCASTLE: Long ago stopped holding sessions in Durham and Northallerton, but continued to use an "Open" prison in West Cumberland, which housed "civil crime" prisoners (bigamy, fraud, etc.).

> Latterly they had noticed an increase in incidence of Hepatitis B markers and discovered that prisoners from Walton Jail (Liverpool) were being sent there for their pre-release 6 months.
>
> This session has now been dropped, so that Newcastle now holds no prison sessions.

From this it is possible that the donor session at the 'Open prison' referred to, continued after 1981. It is not clear from the telephone survey notes when the session was dropped. The Newcastle Centre's records should show when this session was last held.

I recall from informal discussion with staff in the Centre that it was known that prisoners were given privileges for donation such as cigarettes. This went against our policy of not offering inducements to donate.

19. Blood Exports

The export of blood to other Centres requesting it, seemed to be a fairly routine operation. I do not recall any special procedures around it.

20. Publicity

Our publicity program continued as described before. Changes were made in the Donor Services department to provide a small team focused on recruitment. The number of new donors attending had fallen from around 13- to 14-thousand between 1985 and 1987 to less than 12,000 in the following two years. However the number of new donors did increase again with over 15,000 in 1990/91, and around 13,500 in 1991/92 and 1992/93. So it appears that the actions we took in the early years were effective. The table of data 'New Donors Attending & Bled 1985/86 to 1993/94', (WITN6935007) shows the relevant numbers.

We also managed to maintain fairly regular television exposure through, often live, interviews on Regional television programs. To assist with this, I

undertook a short training program on television interview techniques, run locally utilizing the BBC studios in Newcastle.

21. Additional funding for publicity and other questions

21(a) The Northern Regional Health Authority did agree to additional funding for donor recruitment initiatives. A proviso was that we should include a monitoring system to assess effectiveness. I do not recall the details of all the initiatives, but one involved advertising wrap around a local bus, and this in itself generated interest from local television, so increasing awareness. From what I remember, this single initiative did not result in a significant increase in donations in that area.

21(b) The location of donor sessions changed as a result of the loss of industry, as previously described.

21(c) The quality of care delivered to donors.

The Centre did make strides to improve the care at sessions. Firstly by providing information to donors before they attended, fewer ineligible donors attended. This reduces the upset experienced by donors who are rejected, having made the effort to attend, and having waited in-line before being screened by a clerk.

The make-up of staff and equipment per session started to be tailored to the expected size of the session, rather than using a fixed allocation. Other changes included starting a session before its advertised time if everything was in place. Previously sessions only started the process of registering and screening donors from the exact publicized starting time. Similarly the shut-off time for donors which had been rigidly adhered to – if you arrived after the advertised closing time you were turned away, even if it was obvious that the session was still in operation – was modified. A ten minute

cutoff was introduced, again attempting to improve the experience for our donors. We had started to monitor waiting times as a way of understanding what we needed to do to improve the situation.

21(d) The impact of HIV/AIDS

The article referenced in NHBT0005471 from the Sunday Times states:

> 'A significant drop in the number of donors coincided with the onset of Aids'

However this may have been coincidence. I don't recall a study that shows that this was the case. It is possible that there was an association, however the rebound in donations, at least in the Northern Region suggests otherwise, as HIV and AIDS continued to be widely covered in the media.

The document reference NHBT0103431_006 does not add any information about the relationship between donation and HIV/AIDS. It does show the source of the comment reported in the Sunday Times article that 22% of donors who had resigned had only donated once; a survey we carried out on 500 resigned donors from the Newcastle Centre.

22. The 1992-1993 Plan

The increase in donations after the 1998/1999 nadir has been discussed already.

NHBT0103456_004 is an extract from a document I wrote early in my tenure, at a time of falling numbers of donors and a clear need for the Newcastle Centre to increase its plasma production for processing at BPL. It predates the 1992/93 Plan by several years and its relevance to the question about the 1992/93 Plan is unclear.

Nevertheless here is my comment, looking back at that document. I think that I had not yet started to consider the improvements in plasma collection that could be achieved by reducing/eliminating the use of whole blood and by improving operational systems to reduce losses then inherent in the system. As has been noted, the Centre increased its plasma production dramatically over the ensuing years without having to increase the number of donors by anything like the numbers quoted here. A modest plasmapheresis program was introduced.

My memorandum seen in NHBT0046976 shows how the Centre was managing its plasma procurement. The Centre met its target for the 1992/93 year referenced in this memorandum.

The target for the Newcastle Centre for 1992/93 is shown as 34.5 tonnes and the management data for the Centre records that 37 tonnes of plasma was dispatched to BPL that year although as shown in 'Plasma Produced 1991/92 to 1993/94', (WITN6935004), actual production was 34.44 tonnes.

23. Apportioning Production

This question about 'apportioning the blood it [Newcastle] collected to meet … requirements' seems to have no relationship to the question's statement about blood exported.

Before discussing 'apportionment' I can say that exporting blood had no material impact on the production of plasma for fractionation. The table in 'Red Cell Exports 1991/92 to 1993/94', (WITN6935017) shows that in the three years 1991/92 to 1993/94 (I do not have data for other years), almost all the red cell exports had already had the plasma removed. In three years only twenty four units of whole blood were exported, representing an insignificant amount of plasma, around an average of 0.002 tonnes per year compared to the over 30 tonnes supplied to BPL each year.

The document I wrote, reproduced in NHBT0101335_052 has no context, as the document it is a critique of, is not present. I suspect, given the issues raised, that the document it refers to, was prepared by someone without a full knowledge of Transfusion Medicine. Commenting further on it is not of any value.

NHBT0101332_045 is merely an overview of operations with some historical demand data. It was likely a review document I prepared for use by the then Director, Dr. Anne Collins. It does not seem to be relevant to the question as it does not touch on 'apportioning' the collected blood.

As to how the Centre 'apportioned the blood it collected', as an outline, blood would be processed for the preparation of platelet concentrates and a concentrated red cell product as a first call on each day's collection. The provision of platelets being critical, especially with their limited storage time.

As I have discussed already, the amount of the remaining blood that was not processed, i.e. whole blood, was progressively reduced to the point that it became a rarely requested item with no significant impact on plasma production for BPL.

How red cells were separated, such as whether plasma for clinical use (FFP) or plasma in a pack suitable for fractionation was produced, depended on clinical demand for FFP. The fact that FFP is frozen and can be stored for long periods meant that production could be adjusted from day to day without immediately impacting supply for clinical use. FFP met a clinical demand that could not be met from commercial sources or sources other than the Transfusion Centre.

Cryoprecipitate was, like FFP, prepared to meet clinical demand, and as it was stored frozen, production could be adjusted from week to week without immediately impacting supply for clinical use.

As I have noted already, the Newcastle Centre increased its plasma production for fractionation, such that by the time I left the service the quantity of plasma per head of population in its catchment area was close to the top of all Transfusion Centres in England and Wales.

The 1992/1993 plasma production figures, based on tonnes of plasma per million population puts the Newcastle Centre third behind the North London(Colindale) and Yorkshire(Leeds) Centres. Both these Centres had large plasmapheresis operations. Taking only plasma recovered from whole blood donations, Newcastle was the best performer at 10.79 tonnes per million population(t/m) with North London at 10.19 t/m. The average for England and Wales was 8.75 t/m. The poorest performer only supplied 7.75 t/m.

See the table 'Plasma Procurement in England & Wales - 1992/93', (WITN6935011) for full details.

Section 5: Plasma procurement and production of fresh frozen plasma at the Newcastle RTC

24. Production

First, the term 'FFP' was usually used to refer to a product prepared for clinical use and not as a source of material for fractionation, and that is how I have used the term.

24(a) Where plasma preparation took place

In the 'old' Centre, i.e., prior to 1985, plasma was separated in a small suite of rooms in the basement of what was called the Pathology Institute at the Newcastle General Hospital.

The new Centre was well built and generally well designed. A suite of rooms on the main floor was used for the separation of blood into its components. The suite of rooms and the number and quality of

centrifuges used for the separation process were more than adequate and, when opened, the amount of plasma prepared for ongoing fractionation by BPL was well below the facility's capacity.

24(b) The process of blood separation is well documented.

During my tenure the suite was fully redesigned and the facility brought up to pharmaceutical manufacturing standards. As part of the change, a large part of the blood separation was semi-automated with a system that removed most white cells, a cause of many non-specific transfusion reactions. The suite had no difficulty in processing around 35 tonnes of plasma for fractionation annually, as well as preparing platelet concentrates, FFP & cryoprecipitate for hospital use.

To have increased plasma production for BPL would have been possible within the structure of the suite, but dependent on the supply of more donations.

24(c) The proportion of donations allocated to separation into plasma for fractionation and how this changed has already been discussed.

24(d) Further increases in separating plasma for fractionation at the BPL plant would have depended on increasing blood donations and potentially increasing the outdating of red blood cell units, an unethical proposition or increasing plasmapheresis collections.

It should be noted that around 1993 or 1994, BPL reduced its demand for plasmapheresis plasma and proposed reducing the price it paid for this plasma. Due to the more commercial status of BPL, it was competing with commercial fractionators and had no outlet for all the plasma that was available from the Transfusion Centres in England and Wales.

25. RHA decisions in the 1970's

I was not involved in these decisions, indeed in the 1970's I had not stepped inside a Transfusion Centre.

I was aware that a policy not to increase plasma production in the Newcastle Transfusion Centre, but instead fund the purchase of commercially available products existed.

It should be noted that had plasma production been increased in Newcastle at that time, the existing facility at BPL could not have processed it. Any increase plasma supply from Newcastle and subsequent increase in factor VIII for example, would have reduced factor VIII allocation to other Transfusion Centres/Haemophilia units in England and Wales due to the pro rata allocation system.

It may also be of note that my predecessor as Director, Dr. Anne Collins, had shown me boxes of BPL factor VIII in a walk-in refrigerator, that the Haemophilia Centre were, according to her, reluctant to take.

26. Funding for plasma procurement

As far as I know, funding for plasma procurement was part of the Centre's overall budget. What happened in the 1970's and early 1980's is not known to me.

27. BPL Capacity and plasma for fractionation.

During my tenure, there were two programs at BPL to increase capacity – stop-gap 1 and stop-gap 2. I do not recall that these programs affected what the Centre was doing in terms of plasma procurement.

When the new processing facility for BPL opened there was considerable additional capacity and this may have influenced our plasma procurement plans. Without that additional capacity BPL would not have been able to accept the additional plasma.

I do not know whether it affected decisions by my predecessor. Prior to 1985, the poor state of the components production area in the 'old' Centre would have limited developments, but a new walk-in deep freeze unit was installed in the basement, to improve storage of plasma awaiting dispatch to BPL. As such I would conclude that there was some will to increase plasma production prior to the opening in 1985 of the new Centre.

28. Plasma for Fractionation Targets

The document NHBT0001580 (Summary & Recommendations, item 7) shows that in 1980 and still in 1986 the Department of Health's target for plasma production was 8.82 tonnes per million population, which for the Northern Transfusion Service (catchment population c. 3.1m) was 27.3 tonnes (28 tonnes stated in the document). In 1981/82, Newcastle's production of fresh plasma was approximately 6.4 tonnes, rising to 7.5 tonnes in 1984/85. Clearly the Centre's production of fresh plasma was a long way below the DoH target and this shortfall was recognized in the RHA's document (NHBT0001580). There was a steady, if not dramatic increase in fresh plasma over the following four years such that in 1988/89 13.7 tonnes fresh plasma was supplied to BPL.

I also do not know how other Transfusion Centres production compared to DoH targets in the 1980's. If all Centres had met the DoH targets, presumably there would not have been any possibility of BPL processing all the plasma.

28(a) The target did have an impact, as it highlighted the historic poor performance in Newcastle. I wanted to increase production and from what I recall, early in my tenure, the RHA were amenable to changes. The steady increase in production attests to this.

In the next four years to 1993/94 the increases were substantial reaching 35 tonnes that year, up by 157% (1988/89 13.7 tonnes).

Note that plasma production and plasma dispatched to BPL were slightly different measures due to shipment timing and plasma in holding freezers.

28(b) Benefits to exceeding Targets

The impact of exceeding targets would have varied by year and the capacity of BPL. I recall discussing with the Northern RHA whether it might be possible to have some of Newcastle's plasma processed at the Scottish facility at Liberton, so as to obtain additional finished product not then available due to limitations at BPL.

Once BPL's new facility was in full operation, the benefits of meeting or exceeding targets changed once the funding arrangements with BPL changed. Once there was a payment for plasma delivered and BPL had capacity to meet product demand, quotas became irrelevant. If BPL were able to obtain sufficient plasma to meet the demand for its products, which Centre the plasma came from had much less relevance.

For Newcastle as primarily a whole blood as opposed to a plasmapheresis provider of plasma, exceeding the target would appear to be beneficial from a financial perspective. As mentioned before, there is a limit to this approach as more donations are required and potentially red cells would have exceeded demand, an ethically unacceptable situation. This issue did not arise at my time in the Centre.

28(c) Consequences for not meeting the target

As the Newcastle Haemophilia Centre continued to use commercial factor VIII, not meeting the plasma target would have been less of an issue than in some other Centres. I do not know whether the DoH

would have put pressure on the Northern RHA and hence 'consequences' for it.

29. Barriers to achieving plasma targets

- Prior to 1985 – limited and outdated facilities
- The Centre's belief that a large proportion of whole blood was required by the hospitals it supplied.
- Prior to 1988 the RHA's approach to funding plasma collection.

The document NHBT0001580 (probably developed in 1987) indicates that capital investment would be required and that reducing donor enrolment would be a barrier. In the event the decline in donor enrolment was reversed and very little capital investment was required, mainly in setting up a small plasmapheresis unit and some non-recurring funding for recruitment.

The Regional General Managers letter to the DoH shown in DHSC0002247_077 touches on the funding and donor issues.

My predecessor's letter as shown in DHSC0002269_021 does not really add anything.

30. Late 1980's issues

After almost 30 years I can't add anything to what I said at the time as shown in TYWE0000064. Anything further would be speculation.

31. Increases achieved in 1986

This topic has already been discussed.

32. Processing of plasma at the Scottish PFC

As already discussed, this was a possible means to handle increased plasma supply from the Centre and overcome some of the limitations of the pro rata product supply arrangement.

I cannot say why the Northern RHA decided not to progress this stop-gap suggestion.

It is hard to speculate on what might have happened and then extrapolate it to the situation as it was over the next year.

33. 1988 RHA proposal

I was not party to the preparation of this document and cannot say why these statements were made, or the basis for making them.

As can be seen in the press release, I supported proposals for a modest investment in plasmapheresis (NHBT0072037).

34. RHA – Increase in plasma collection target

This has been discussed before.

The Centre was successful in meeting these targets.

35. Plasmapheresis

As noted in 33 above, the Centre discussed with the Northern RHA starting plasmapheresis for plasma for fractionation. The RHA allotted capital and an initial program was started.

35(a) For any 'quantity' program, machine plasmapheresis was the only viable option.

35(b) I do not have figures for the difference.

35(c) The centre had many experienced and skilled staff. Introducing a plasmapheresis program was well within its capabilities.

35(d) 'whether, in your view, plasmapheresis would increase the amount of available plasma'

I can't think of what else it would do.

36. Plasmapheresis Station

The 'Plasmapheresis Station' was a plan put forward by my predecessor but which was never executed.

A plasmapheresis operation was started within the new Transfusion Centre (opened 1985). The new Centre, as designed, incorporated an area for conventional blood donor sessions, with a small bay for plasmapheresis (two couches). In the event the donor session area and the plasmapheresis bay were combined and used for plasmapheresis. I do not now recall if this happened immediately on the opening of the new Centre, or later.

I do not remember the date when the plasmapheresis unit started operations, however, I see that it was operational during the years 1985/86 and 1986/87 at a very low level, with increases starting in 1988/89 presumably due to the new funding referenced in 35 above. The table 'Plasmapheresis Donations 1985/86 to 1993/94', (WITN6935012) shows the activity and collection volumes over these years.

The proportion of the plasma to BPL that the plasmapheresis program supplied declined as the amount of plasma recovered from whole blood increased, although the program continued at about the same level until issues at BPL forced the cut-back of the plasmapheresis program.

37. Plasmapheresis Comparisons

I am not in a position to make comparisons as then existed when the program was started. I knew and had visited some Centres with quite extensive plasmapheresis programs. These were automated plasmapheresis programs and Newcastle used the same or similar equipment to them.

The operation in Newcastle was small by comparison to say, the Centre in Leeds. From the table 'Plasma Procurement in England & Wales - 1992/93', (WITN6935011) you can calculate that in that year, the Leeds(Yorkshire) plasmapheresis program produced around 4 tonnes of plasma per million population, whilst Newcastle was producing about 1¼ tonnes per million population.

The area used for plasmapheresis had eight or so plasmapheresis machines, and initially had a separate post-donation rest room on the other side of the corridor. Later, in consultation with the staff in the unit, the area was redesigned with new clerical and rest areas all within the same space. This made the unit easier to operate.

38. Interaction with hospitals to use less whole blood.

This has already been discussed.

Meetings with haematologists and blood bank staff from across the region were key to the almost complete elimination of the use of whole blood.

The chart 'Percentage of Red Cells Issued as Whole Blood 1985/86 to 1993/94', (WITN6935002) shows the change from just over 60% in 1985/86 to effectively zero by 1993/94.

Section 6: Arrangements for the supply of FFP to BPL

39. Pro rata System

The pro rata system has been referenced in relation to several questions already.

39(a) Why Introduced

I do not know who proposed the arrangement or when it was first introduced. I can only make an informed guess as to why it was

introduced or formulated as it was. I am sure there are individuals better informed than myself to answer this question.

However I do note this item extracted from document CBLA0001287, dated March 1981, minutes of the second meeting of the Advisory Committee on the National Blood Transfusion Service and marked 'Not for Publication':

> MINUTES OF THE SECOND MEETING HELD ON 23 FEBRUARY 1981 AT THE DEPARTMENT OF HEALTH AND SOCIAL SECURITY, HANNIBAL HOUSE, ELEPHANT AND CASTLE
>
> PRO RATA SUPFLY OF BLOOD PRODUCTS ~ AC(81)3
>
> 6. The Chairman explained that the pro rata distribution of certain blood products was due to start from 1 April 1981 and Paper AC(81)3 set out those issues on which the Department sought the Committee's advice, particularly in relation to supplies to special units. Mr Godfrey emphasised that the Paper's appendices were intended as a broad illustration of how pro rata distribution would affect the level of supplies to RHAs. Dr. Lane would be meeting RTDs to discuss allocations in detail.

39(b) How the pro rata system worked.

The system had many nuances and its impact on supplies varied over time. If a product from BPL was available in excess of demand, then the pro rata distribution had no effect, whilst for products where supply did not meet demand the pro rata arrangements had a significant impact.

39(c) Advantages and Disadvantages

The advantage of the system was to apply a formula to the distribution of limited supplies across England and Wales. As to disadvantages, it depended on your individual situation. As seen in the table 'Fresh Frozen Plasma to BPL 1981-1985', (WITN6935013), a static production of plasma could still lead to a drop in supply if other Centres increased production. In that period despite

Newcastle's production remaining constant, the pro rata percentage fell from well over 5% to around 3%.

You could question using a system designed to apportion limited product, as an incentivizer to production.

39(d) As seen in the RHA's planning document NHBT0001580, COLLECTION OF FRESH FROZEN PLASMA IN THE NORTHERN REGION [Note: This is an RHA planning document for 1989/90, probably completed in the last quarter of 1988], there is evidence that the limited distribution of product to the Northern Region through the pro rata system had an impact on the RHA's planning:

> 15 The main reason for seeking self sufficiency is to guarantee a proper product level to meet Clinical needs. However, the cost of commercially purchased products is already higher than at least the first phase incremental costs of increasing collection so there is also a financial incentive.

39(e) As haemophilia treatment products were managed by the Haemophilia Centre and its pharmacy department, the impact of changes in the supply of BPL product cannot be assessed (by me). Similarly products such as Albumin also available from commercial sources were purchased by individual hospitals and I am not able to provide an assessment of the impact of the pro rata system on them.

39(f) As has been discussed before, whilst the Newcastle Transfusion Centre, prior to my time as Director, had a relatively static production of plasma, the amount of plasma received at BPL from all other Centres increased. Hence Newcastle's pro rata allocation of finished products declined, as can be seen in the table 'Fresh Frozen Plasma to BPL 1981-1985', (WITN6935013).

In four years, with no change in production, Newcastle's proportion of fresh plasma declined by over 50% (5.65% to 2.64%). The

proportion for 'all plasma' which included time-expired plasma was less dramatic (6.5% to 4.8%). The fresh plasma change would have affected the pro rata distribution of coagulation factors, notably fVIII.

40. Cross Charging

NHBT0057426_002 sets out the rationale for cross-charging as it was called. That document answers most of the issues about how it worked.

40(a) As noted in answers to the last question, the pro rata system had many nuances, depending on demand for product, production capacity and the use or preference to use commercial or BPL products.

40(b) I don't have a strong view on this issue.

40(c) I do not recall, or was not aware of how prices were determined.

40(d) The Newcastle Transfusion Centre continued on its plan to increase plasma, primarily by reducing the amount of whole blood and secondarily by improving its quality systems and reducing waste. The cross-charging system did not alter this.

40(e) I do not recall a specific impact on the supply of BPL products to hospitals in the Northern Region. There may have been, but it was not something that I was aware of.

40(f) As per my answer in 40(e). above, I am not aware if there was a change.

40(g) This is outside my area of knowledge.

41. Effect on Plasma Supply in England and Wales

This is outside my area of knowledge.

42. Bilateral Agreement

42(a) The purpose is set out in NHBT0097053_045. I cannot add anything useful to that document.

42(b) My letter to Dr. Moore at the National Directorate as shown in document NHBT0097035_067, clearly shows my position and the reasoning behind it.

I note that I was not alone in not supporting this arrangement. In a Northern Division meeting of 15th February 1990, NHBT0070258, there is the following:

> Dr. Wensley reported discertingly [sic] from a recent Haemophilia Directors meeting. There is no committment to buy NHS Factor 8. NHS Factor 9 is regarded as an outdated non-pure product.
>
> Dr. Lee reported that only 70% of BPL products appear to be taken up.
>
> A possible agreement that the RTCs have a committment to take a certain amount of BPL products was not welcome.

42(c) I do not recall how the eventual contract was determined. No doubt there is some documentation on the issue. I do not recall any significant issues arising from the ensuing arrangements.

Section 7: Production of cryoprecipitate at the Newcastle RTC

43. Cryoprecipitate Production

43(a) Cryoprecipitate was produced in the components department as with other components such as platelets, FFP and plasma for fractionation.

43(b) The preparation of cryoprecipitate followed standard methods of freeze/thaw/separation.

43(c) The amount of blood collected each day that was used for the preparation of cryoprecipitate depended on the amount in stock. Cryoprecipitate was used locally and was not sent to BPL.

43(d) The cost of cryoprecipitate preparation was part of the normal operating budget, although prior to my involvement in the Transfusion Service, its production was dependent on the availability and funding of the then new plastic bag systems for blood collection, at a time when all other donations were collected into glass bottles.

43(e) I do not have sufficient knowledge of the system in the early 1980's to answer this. During my time as Director/Chief Executive, additional cryoprecipitate could have been made on a week by week basis. I am not aware of any shortages of this product.

44. Cryoprecipitate Demand

NHBT0101332_045 has some data that I prepared showing cryoprecipitate production between 1982 and 1985 as shown in table 'No. of Units of Cryoprecipitate Produced 1982 to 1985', (WITN6935014), where production ranged around 5,000 units per year.

The following comment was included in my report in NHBT0101332_045:

> This, however, hides an underlying trend. The major users were the haemophilia units at Newcastle and Middlesbrough. The use of cryo at the R.V.I. fell significantly in 1983 and 1984, probably due to a reduction in surgery on haemophiliacs due to HIV/HTLV III positivity. It seems likely that orthopaedic surgery will increase again as arrangements are made to carry out surgery on HIV/HTLV III positive patients.

The production of cryoprecipitate however continued at similar levels over the next few years, averaging just over 5,000 units per year as shown in the table 'Cryoprecipitate Issued 1985/86 to 1993/94', (WITN6935015).

45. Family-specific Cryoprecipitate

As shown in NHBT0078890_022, the Centre was able and prepared to make cryoprecipitate from parents for their children. I don't recall how often this happened, but it was not a common event.

The decision to undertake this procedure was clinically driven, as shown in the letter, by Dr. Peter Jones, the Haemophilia Centre Director. The Transfusion Centre had the facilities and expertise to carry this out.

46. Quality of Cryoprecipitate

The audit shown in document NHBT0073105_001 occurred shortly after I became Director. I was aware of issues with the production of components including cryoprecipitate. Changes in the standardization of procedures, associated staff training and the development of a quality control system within a comprehensive quality assurance program was undertaken. You may have access to later MCA audits which would confirm the progress made.

46(a) The exact conditions for the production of blood components including cryoprecipitate will affect the end product, hence the standardization of production, detailed production methods set out in controlled documentation, training of staff to those standards, internal audits of conformance to set methods was necessary. This was monitored by regular analysis of produced products.

46(b) The Centre made major changes to its production arrangements, including, as indicated above, training and the preparation and upkeep of standard procedures (Standard Operating Procedures/SOPs). A new Quality Assurance department was created. These changes were made within our existing budget.

46(c) I do not recall being aware of issues with the cryoprecipitate prepared by the Newcastle Centre being raised by the Haemophilia Centre Director or other clinicians.

46(d) After the changes outlined above, the internal quality assessments of the product (carried out on a statistical basis) did not, as I recall, give rise to further concerns. A review of later MCA audits may help, but I do not have access to these or to the regular Quality Assurance department reports that were prepared in the Centre.

Contracts with hospitals, as seen in this extract 'Supply Contract Audit' (WITN6935034), from a 1993 draft, included information on standards and offered hospitals the opportunity to audit the Centre's preparation of blood and blood components:

> 8. External Audit
>
> As a supplier of Blood, blood components and reference facilities … we will be happy to provide facilities for your staff to carry out an audit of our Blood Collection, component preparation, testing, storage and distribution system.
>
> … Alternatively, units may accept the Audit carried out by the Medicines Inspectorate as satisfactory evidence of conforming to standards and to Good Manufacturing Practice … .

46(e) I do not recall the Newcastle Haemophilia Centre commenting on these matters.

Section 8: Arrangements for obtaining and allocating blood products at the Newcastle RTC

47. Relationship with the Haemophilia Centre

The Haemophilia Centre(HC) requested product prepared by BPL, including fVIII and fIX from the Transfusion Centre (TC). The TC dispatched product to the HC as available. The HC were aware of the quantity of BPL product

supplied under the pro rata system. Sometimes it was necessary to remind the HC that factor VIII was available.

Cryoprecipitate was requested through the blood bank at the Royal Victoria Infirmary, per normal procedures for obtaining blood and other locally prepared components from the Centre.

48. Responsibilities of HC to the TC

I was not aware of any set of responsibilities.

49. Management Roles

The HC and the TC were two independent facilities. Both had their own management arrangements. My dealings with Dr. Peter Jones were both professional and amicable. I do not recall any disputes arising.

50. Disputes

In my statement shown in TYWE0000067 I stated:

> I am not aware of any difficulty or dispute which has occurred, either since my appointment or during Dr. Collins' period as Director, concerning the supply of blood products (whether Factor VIII, Factor IX, or otherwise) to the Newcastle Haemophilia Centre.

I do not recall any disputes arising at a later date than that referred to in the above document

51. FFP and Cryoprecipitate Supply

Hospital blood bank staff contacted the Transfusion Centre to order these products as required. Depending on when the product was ordered, the order would be supplied to the hospital as part of a Transfusion Centre regular delivery using a Transfusion Centre vehicle, or if required before the next regular delivery, it would be dispatched according to the hospital involved. Hospitals in the Newcastle area were supplied by a Transfusion

Centre van, whilst for other hospitals the order was typically dispatched by an express rail parcel service. Sometimes a hospital would opt to send one of its own vehicles to collect the products.

As both these products are stored deep frozen and have long shelf lives, most orders would be included in regular deliveries by Transfusion Centre vehicle.

52. Acquisition etc.

I don't have any additional comments to make.

52(a) The Newcastle Haemophilia Centre, throughout my tenure and during that of my predecessor.

52(b) Responsibilities have already been covered.

53. Purchase etc. of commercial blood products

As stated in the question:

> … staff of the Newcastle RTC took no part in the decision to purchase commercial Factor VIII, and that all purchases were made by the Pharmacy Department at the Royal Victoria Infirmary.

This applied to all commercial products used by the Haemophilia Centre.

54. I was not party to decisions on the purchase etc. of commercial blood products.

The question: 'Please elaborate, as far as you are able, on the arrangements in place in the Northern region for the purchase, storage, and allocation to haemophilia centres within the region, of commercial factor concentrates and/or other blood products ("commercial blood products").' was answered in my statement made in 1989 and shown in document TYWE0000067, as follows:

With regard to the purchasing of commercial Factor VIII, the present position is that all purchases of this blood product from the commercial market are currently made by the Pharmacy Department at the Royal Victoria Infirmary. I am not sure what precisely is the relationship between the Pharmacy Department and the staff at the Haemophilia Centre. I am also not sure whether acquisitions of commercial Factor VIII have always been made through the Pharmacy Department, or whether at some point in the past, such purchases were made directly by the Haemophilia Centre.

At all events, it is true to say that the Northern Region Transfusion Centre staff had no participation in either the decision to purchase commercial Factor VIII, or the choice of source from which commercial Factor VIII would be obtained.

As the Newcastle Centre had no active role in the supply or use of fractionated products, either from BPL or commercial, by haemophilia centres, there were no meetings that I recall.

55. Other Regions

I was not party to the arrangements in other parts of the country.

56. Direct Supply of BPL Products

As noted in a note of a meeting I attended shown in NHBT0118272, Newcastle was one of the Transfusion Centres that stopped handling BPL's products. BPL would now deal directly with hospitals. As noted before, Newcastle's participation in handling BPL products was as a passive stock-holder, although with the change in financial arrangements with BPL, the Centre was paying BPL for the products and passing on the cost to hospitals who were purchasing them. In my letter to the Haematologist at a major user of BPL Albumin products as shown in NHBT0072681, the Centre's role in the supply chain from BPL was becoming untenable. As BPL assumed a more commercial role, the role of the Transfusion Centre in the chain was something of an anachronism.

The requirement to be licensed was also mentioned:

> We will have to pay for a Wholesale Dealers licence for BPL products for 1992/93 and this cost will have to be borne by the Region. The licence will lapse with effect from 31st March 1993.

The aforementioned letter also notes that the hospitals In Newcastle would no longer be purchasing Albumin products from BPL. I assume, but have no record available to me, that other hospitals in the region would continue to purchase some or all of their Albumin products from BPL.

57. Contracts for Imported Blood Products

The Newcastle Centre did not at any time participate in purchasing 'imported blood products' from pharmaceutical companies.

Note: Reagents used in testing blood etc. were purchased from companies importing the product from outside the UK. Some of these would have contained human-sourced components. They were not used clinically.

58. Influence

As already stated, the Newcastle Centre did not at any time attempt to influence haemophilia clinicians in the use of products for their patients.

I have already noted that it was necessary at times to remind the Newcastle Haemophilia Centre that deliveries of factor VIII from BPL were waiting pick-up or instructions for delivery. How, or if, the Haemophilia Centre used this product was entirely in their jurisdiction.

59. Factor VIII use in the Northern Region

I do not recall the source document for my comments on factor VIII use across the country. I do however recall that the Northern Region had a higher usage. As to my comment:

> For various reasons, however, it did not follow that the short fall in demand in the Northern Region for NHS produced Factor VIII was greater than elsewhere.

I am not sure what point I was trying to make at that time.

60. Untoward Use

I am not qualified in the management of haemophilia and cannot comment if the use of factor VIII was 'in any way untoward'.

61. Preference for Commercial Product

I do not have anything further to add.

62. Choice – Key Factors

I am not qualified in the management of haemophilia and cannot comment on the factors influencing haemophilia specialists in the use of different products.

63. Cryoprecipitate

63(a) The issues around the production of cryoprecipitate have already been discussed.

63(b) The issues around the production of cryoprecipitate have already been discussed.

63(c) ' ... whether the Newcastle HC ever encouraged the Newcastle HC to support the production and use of cryoprecipitate.'

I am not sure what this means. Production and Use are separate issues managed by separate entities. As noted previously, the Newcastle Centre could have increased cryoprecipitate production if demand warranted it.

64. Insufficient supply of NHS blood products

The amount of factor VIII from BPL was for many years limited. Newcastle in particular having less due to the pro rata arrangement and limited plasma procurement.

If there had been a decision by the Northern RHA to invest in plasma procurement in the early 1980's then more factor VIII would have been available. However as noted before, any increase in supply to Newcastle would have resulted in less in other parts of England and Wales. My understanding was that prior to the new BPL facility, BPL could not meet the whole demand, hence the pro rata distribution.

I do note in the Background section of a Northern RHA report (NHBT0001580) there is this statement:

> In the late 1970s, the demand in the Region for FVIII increased rapidly, exceeding the available supply from the Regional Transfusion Service. At that time, a decision was made to purchase commercial FVIII, rather than invest in plasma procurement through the RTC.

The supply of NHS fVIII increased with the opening of the new BPL facility, and taken together with the increase in plasma from the Newcastle Centre after that time, it is possible that NHS fVIII could have met the Haemophilia Center's requirements for this product.

65. Standards

I am not qualified in the management of haemophilia and cannot comment on the standards of different factor VIII products.

66. BPL product in store

66(a) It is not possible to say how often shortfalls of BPL's factor VIII occurred. The Centre was a passive intermediary in the system between BPL and the Haemophilia Centre.

66(b) The Haemophilia Centre did not order fVIII from the Transfusion Centre and the Transfusion Centre did not fulfill orders. As a result there was no 'generally in stock' situation.

66(c) I cannot say how often the Haemophilia Centre was requested to collect BPL fVIII.

66(d) I never made any requests personally to the Haemophilia Centre to collect BPL fVIII and so cannot say how they responded. I do not recall my predecessor, Dr. Anne Collins, commenting on any response when she had called them.

67. 1988 demand for Factor VIII

Please explain why a high number of haemophiliacs infected with HIV would lead to a decrease in demand for Factor VIII.

In my June 1988 document NHBT0103458_001, there is this paragraph:

> I note in paragraph 1.4 that the demand for coagulation factors is still growing. I have discussed this recently with several of the other RTCs, and it would appear that this region is unique in the current fall in demand for factor VIII. I presume that this is because we have far more haemophiliacs infected with HIV than is the case in other regions.

My understanding was that with so many haemophiliacs infected with HIV, much of the routine surgery, such as joint replacements that required very large quantities of factor VIII would cease. There was also the unfortunate consequence of a high proportion of HIV infected individuals that the onset of AIDS would lead to premature deaths.

68. Clinical Freedom

I have looked at both documents referenced (NHBT0047289, and SBTS0000097_022), however I don't have anything further to add on Clinical Freedom.

Section 9: Self-sufficiency

69. Self sufficiency

I used the term 'self-sufficiency' to refer to the provision of plasma for processing at BPL which would result in fractionated products available in the Northern Region in sufficient quantity to meet demand.

Self-sufficiency typically referred to the availability of factor VIII, although this definition is problematic given the limited use of BPL factor VIII in the Region.

If you look at self-sufficiency at a country level (England & Wales) where BPL becomes self-sufficient when it has enough plasma to manufacture all the products it can 'sell' to hospitals, we get into issues of whether non-BPL product should be constrained in order to allow BPL to supply more.

There was then the issue that as BPL dealt directly with hospitals, the link to each Regional Transfusion Centre's plasma production became much weaker.

70. Transfusion Centre & Haemophilia Centre – self-sufficiency concept.

I cannot talk to the issues of self-sufficiency from the perspective of the Haemophilia Centre.

My responses here refer to my experience at the Northern Region Blood Transfusion Service.

70(a) Plasma procurement and self-sufficiency is a thread that has run through many of my answers.

70(b) Cryoprecipitate production is unrelated to issues of self-sufficiency in products prepared by BPL.

70(c) I have had no part in the purchase of commercial blood products.

70(d) Funding issues have been discussed before.

The Northern RHA's funding of the Transfusion Centre during my tenure allowed the Centre to deliver amounts of plasma to BPL that would meet conventional concepts of self-sufficiency.

71. Prospects of achieving UK self sufficiency

My views on this depend on when the question was being asked.

My letter to the National Directorate in 1990 (NHBT0097035_067) shows that BPL was producing more product than the NHS in England and Wales was prepared to purchase. By at least one definition, self-sufficiency had at that point been obtained and Transfusion Centres would not need to provide any further increase in plasma for use by BPL.

I did not know enough about total demand in England and Wales, or have information on commercial product purchases to be able to say whether BPL could have supplied all demand. It would appear from the table 'Plasma Procurement in England & Wales - 1992/93', (WITN6935011), that had all Transfusion Centres met at least the non-plasmapheresis production rate of 9 tonnes per million population (8 of 14 Centres were achieving this and four Centres were at 10 tonnes per million or more), then an extra 32 tonnes of plasma would have been produced for a 1992/93 total of almost 560 tonnes. See Table 'Theoretical Plasma Procurement at a Minimum of 9 tonnes/million', (WITN6935016). I personally do not know if 560 tonnes would have met all demand or whether BPL could have processed this amount, but it should have been possible to reach this amount. From NHBT0097035_067, it appears that in 1990 BPL was processing no more than 490 tonnes.

72. Accord with peers

I don't know how other Centre Directors/Chief Executives viewed self-sufficiency. Perhaps when I was in post I would have been able to comment further, but now I cannot say.

73. Haemophilia clinicians support for UK self sufficiency

I don't know what their views were on this topic or indeed on self-sufficiency at the BPL English/Welsh level.

Section 10: Services for donors at the Newcastle RTC

74. Counselling Offered pre HCV/HIV/HBV testing.

I am not clear what this question means. Blood donors were not counselled before they gave blood.

I do note that a draft for the 1992 donor health questionnaire, 'Health Questionnaire 1992 Draft', (WITN6935021), shows that donors were informed about testing:

> I agree to my blood donation being tested for the AIDS / HIV virus and other infections

I do not recall whether this or similar wording was in place before this.

75. Counselling offered for HBV and HIV

Donors found to be HBV positive were informed by letter and by letter to their General Practitioner. If I recall correctly, the donor was encouraged to contact their General Practitioner, and the letter to the General Practitioner included information about a Consultant Hepatologist, and a request to refer the donor to them.

The document 'Positive Donor Letter', (WITN6935035) gives an idea of what was used in Newcastle to contact donors. This was a draft that I prepared for use by Dr. Collins to contact donors who had tested positive for HCV during

the first generation trial and was likely modeled on the correspondence used for HBV positive donors. (The reference on the draft DCH10031/HLL/pk, shows that it was written by me).

With the advent of HIV testing the number of positive donors was very small. Certainly in the early days I arranged to see each positive individual and had pre-arranged a meeting with an infectious disease specialist based at Newcastle General Hospital on the same day.

As noted in an external review (NHBT0009710):

> One Consultant has overall responsibility for counselling of donors for HIV. Such donors are seen on a one-to-one basis and referred on to the Consultant Physician in Infectious Diseases at the neighbouring hospital.

76. Recipients of Infected Donations

As far as I recall there was no involvement of the Centre in the care or counselling of infected recipients. A recipient was a patient of a hospital specialist.

77. Sufficient Arrangements

The arrangements for HIV positive individuals was I think acceptable, with the individual being passed to a well-respected specialist.

As to HBV there was no follow-up to ensure that each 'test-positive' donor had been seen by a specialist, and a system of follow up to ensure this, might have been appropriate.

78. HCV Follow-up

78(a) There was a health problem. During this period Dr. Collins had asked to take on more responsibility, unfortunately it turned out that she was unable to manage her existing responsibilities.

78(b) All donors who had donations that were positive were removed from the donor lists and identified on the computer system as Infectious Disease positive. None would have been able to donate again.

78(c) The impact of the delay is hard for me to quantify. I am not an hepatologist and thus I cannot give a sound clinical response.

Section 11: Meetings of various committees

79. Final RTD meeting

Having attended only one of these meetings I am limited in what comments I can provide. However it appears that they provided an opportunity to hear how other Transfusion Centres approached issues and when new issues arose or new proposals were being made that would affect all Transfusion Services it was helpful to hear from the widest possible range of individuals. Being restricted to meetings within a small group of Centres removed a valuable source of information.

The loss of direct access to senior DoH representatives and the Director of BPL, would appear to have been a backward step.

80. Decision Making

I was not aware that this meeting had a decision-making remit.

I note that at the last meeting this comment was made:

> The Committee Structure associated with the National Directorate was welcomed and as the discussion of a medical/scientific RTD Meeting developed it became clear that any managerial role for the RTD Meeting was regarded as superfluous.

81. Fulfilling the purpose(s) for which they were established

I do not recall seeing a document that describes the purpose of these meetings. As such it is hard to say if they fulfilled a particular purpose.

82. Reason for Abolition

I don't know why the RTD meeting was abolished. I thought that it was a bad move. I note that the decision to abolish the meeting was 'unanimous'. I am not sure that I would accept this statement.

In the document SBTS0000628_0 which contains 'informal' minutes taken by the SNBTS representative, there is the following:

> Dr. Smith (whose last meeting it was) recommended an annual meeting of Transfusion Directors to discuss matters of major policy.
>
> Dr. Wagstaff considered that the RTD meetings were still useful for comparisons and exchanges of view.
>
> Dr. Wagstaff invited comments and objections but did not ask each Director individually. Some Directors were absent, being represented by deputies (...) ;
>
> There was no discussion of the advantages and disadvantages of dissolving the RTD meetings.

In comments to the informal minutes (in the same document) there is this:

> On the minus side there is now no formal locus for the English RTDs to meet together with representatives of DHSS and BPL, not to mention Scotland.
>
> ... and in the midst of a slightly non-plussed silence, Dr. Wagstaff concluded that the 210th was to be the last RTD meeting in its present form.

83. Further meetings

A regional meeting was implemented involving Directors from the north of the country. From what I recall and based on comments by Dr. H. Gunson, as seen in NHBT0018188, part of section 4 a, the work of the National Directorate would be isolated from the Centre Directors.

The following are extracts from the minutes of the last meeting:

> Dr. Gunson pointed out that the regular slot on the Agenda for BPL update would no longer be necessary because of the creation of a CBLA/NBTS Liaison which

would meet regularly, probably quarterly and report to the National Management Committee.

Dr. Gunson confirmed that contact with the SNBTS would be maintained by regular Meetings between himself and Professor Cash.

Dr. Pickles confirmed that the DOH accepted the changes and Dr. Gunson confirmed three avenues of communication with the Department which would be maintained, i.e. direct contact between himself and Dr. Pickles and between Dr. Moore and Mr. Canavan; via the NHS Management Board Co-ordinating Committee; via the annual report submitted by the National Director on Management Objectives in the NBTS.

84. See 83 above.

85. I don't have any comments on these meetings.

86. See 85 above.

87. See 85 above.

88. No.

89. I don't think that I can add anything of value on this issue.

90. Meetings after the formation of the NBA

I presume that records of NBA meetings exist.

I attended meetings at the NBA office in Watford on quite a number of occasions, but these were not 'Divisional'.

Section 12: Information handling by and information sharing between RTCs

91. Donor/Donation Record Keeping

When I took up my position as Director, the primary donor records consisted of a long-standing card known as the 101. These cards were maintained in large electro-mechanical machines that allowed access to trays of records

stored by donor session. Once a donor had made a certain number of donations and the card was full, a further 101 was stapled to the original.

A second (duplicate) set of 101 cards was maintained for each donor. The duplicate was actually the first 101 card allocated when the donor made their first donation. It was buff coloured. Once the new donor's blood group had been determined a substantive coloured 101 would be prepared and became the primary record. The colours followed the old blood group label colours, blue for group O etc.

Prior to my first period at the 'old' Transfusion Centre, the IT department at the Northern RHA had created a computer program to hold the donor records. However the program did not have enough functionality to replace the 101 cards. Its main use was to print labels for invitations to be sent to donors. It only had capacity to hold information on four donations and only a single entry for virus testing results for each of those donations.

This setup was archaic even in 1981.

The RHA did look at providing additional computerization and a proposal was made by the RHA's IT department for a computer program housed at the RHA, where daily results would be sent to them for input each night on a batch processing basis. Fortunately this came to nothing. A further look at available computer systems took place in the mid 1980's but came to nothing.

At the time of the audit referenced (NHBT0006234) the 101 card system was still in place and laboratory records were almost entirely manual. Component production records had been computer generated for a few years on a stand-alone system. This had eliminated the record keeping errors in this area that were due to number transpositions and the like.

There was little in the way of access control at that time (1985).

Subsequently, donation records were computerized and there was strict access control to the physical computer hardware. The IDM and Abbott systems had user access control, transaction logging and the systems had no external connectivity.

With the implementation of a records policy, the main records room was secured.

Access control to and within the building was improved with keypad access to external doors and to certain internal areas. The public entrance was redesigned to ensure that visitors could not gain access to the building beyond the entrance lobby.

92. Duration of record keeping

As far as I could tell, records were kept for as long as storage space was available. I am not aware of any policy for destroying donor records, and resigned/inactive donor records were retained.

93. Record keeping practices

See above.

94. Other RTC's

Other RTC's were at different stages of changing their donor and laboratory record keeping, with some at the time of the mentioned audit still using the 101 record cards.

95. Medicines Inspectorate Audit 1989

95(a) The record keeping system had been in place for many, many years. It was certainly difficult, but not impossible to trace the disposition of donations. Internal audits confirmed that tracing worked but in some cases could be very slow.

95(b) The system was slow, but having been in place for many years, was well understood by the staff and fully capable of ensuring that donors identified as infectious were rejected. If a donor made a donation at a different site to that normally used, their donation would be rejected before authorization for use.

95(c) The system was adequate but slow, and donations could be traced.

96. Improvements

As noted above, I and the management at the Transfusion Centre recognized that there was an urgent need for an integrated computer system. After research of available systems it was decided to implement a system developed by IDM and already in use in the United States. As a policy, the Centre would no-longer write its own software or have software developed for its sole use.

The new system was extensively validated before being introduced.

The IDM system integrated directly with the computer management system used by the proprietary infectious disease testing system, having been written by the same company.

Between the time of the afore-mentioned audit and the decision to purchase the IDM system, an in-house developed system was introduced (April 1991). Document NHBT0074034_001 refers to this:

> This Local Area Network (LAN) is an in-house developed system covering all component production work, the testing of all donations, the associated clerical work and medical information and the verification, labelling and dispatch of all units of blood and blood components. It records all donations made, registering information about the blood packs, their type and their Lot or Batch Numbers.

97. Records Retention Working Group.

Together with two members of staff at other RTC's, Dr. Alan Beal, & Mr. Tony Martina, a report on record retention was prepared for the National Directorate.

The system described in the report, including working within a formal written policy and with records of document destruction (within the policy) being maintained was implemented in the Newcastle Transfusion Centre, although we did not have off-site storage.

I have no information on record keeping at other Transfusion Centres or whether the recommendations were acted upon by the National Directorate.

98. New Obligations

The Centre always considered new legislation such as the Product Liability directive. Dr. R. Doughty, Laboratory Manager and later Operations Manager was particularly good at keeping abreast of new legislation and identifying issues that the Centre should address.

99. CDSC Database

I was aware of CDSC holding information on HIV positive individuals, at least due to the letter shown in document DHSC0020840_031.

I do not recall how this was followed up or if we supplied information to CDSC.

Presumably their records would show if information was forwarded from Newcastle or from Newcastle via the National Directorate.

I am fairly sure that the Centre did not maintain a separate database 'to track HIV positive donors'. I cannot see that there would have been any need to create a separate database.

100. J Donor System

I was not aware of the 'J' donor system. It looks as though it was a system specific to one Transfusion Centre, possibly Manchester.

101. Anti-HCV database

I do not recall this arrangement.

102. Donor black list

I do not recall such a system. Records from the National Directorate would provide further information.

103. Sharing Information on Excluded Donors

I do not recall that the Centre shared such information.

104. No Central Organization

The issue of a central organization for Transfusion Centres that ensured uniform operations is outside my area of responsibility. I have previously commented on the use of standards and MCA inspections to ensure uniform outcomes.

Section 13: Knowledge of risk of infections while at the Newcastle RTC

105. HIV Transmission

At the time I became a Consultant Haematologist, I was fully aware of the risk of transmission of HIV by blood transfusion, by individual blood components and through fractionated products. See 106 below.

106. HIV and Blood Transfusion

I don't recall when I first became aware of this, however in 1985 I made extensive notes on HIV entitled 'The Acquired Immunodeficiency Syndrome and the T-Lymphotrophic Leukaemia Viruses'.

This was dated 14/4/85. See 'AIDS Notes 1985', (WITN6935027).

In my handwritten document is included this:

> Mode of Transmission
>
> ... The transmission by blood or blood products is now well documented and this includes ... patients receiving blood or certain blood products. ... Factor VIII concentrate is known to transmit HTLV III and one case is documented of a patient who had received only U.K. produced fVIII concentrate developing AIDS.

107. Risk NHS Products vs Commercial

There was no use of commercially prepared blood products such as FFP or Cryoprecipitate or of course red cell preparations.

For fractionated products I was aware of a much higher risk associated with commercially prepared ones.

Despite this I was aware of the risk to any products prepared from plasma pools including those prepared by BPL. Although it appears that BPL factor VIII (pre-heat treatment) was safer, it could not be considered free of risk.

The situation changed with the introduction of heat treatment.

108. Risk of transmission of HIV/AIDS Studies

The meaning of the question is unclear '... risks of transmission of HIV/AIDS.' AIDS is not a transmissible disease. What transmission risk is being examined?

109. AIDS Clinical Care Group

I do not recall if I attended this group.

110. Knowledge of hepatitis

I was aware long before the identification of the hepatitis C virus that hepatitis occurred in a few individuals post-transfusion even after the introduction of tests for HBV. Patients undergoing open-heart surgery requiring large amounts of blood, FFP and platelets were known to have a higher risk of hepatitis. As markers for HAV and HBV viruses were negative, the agent was referred to as non-A, non-B (NANB).

In July 1989 I attended one of the first scientific meetings in the UK where the discovery of an agent responsible for a large part of the non-A, non-B infections, and called HCV was presented. I made notes of the meeting, see 'Sheffield 1989 HCV Notes', (WITN6935032) and the following was my summary:

SUMMARY

A non A, non B Hepatitis virus has been characterised and termed Hepatitis C virus (HCV). The mode of transmission of this small enveloped RNA virus is not known, other than by blood and blood product transmission. Other transmission occurs and there is speculation that it could be tick or mosquito borne because of some (relatively remote) similarity to the Flavi viruses, which include the mosquito borne Yellow Fever Virus. Sexual transmission is not a major route of infection, An antibody test using a recombinant Antigen has been developed. The test appears quite specific but does not test positive in all cases of NANB. In acute, resolving NANB only some cases seroconvert but in chronic cases the test is positive in 50 - 90% of patients. About 0.5% to 8.0% of healthy blood donors are positive, the higher percentages being found in some specific groups studied at the New York Blood Centre. Their average positivity rate was 1.4%. In Barcelona 1.0% of donors were positive and preliminary, unpublished data from the U.K. suggests that 0.5% of donors are positive.

The surrogate NANB tests, such as the Liver Enzyme ALT and Hepatitis B core antibody, do not detect many who are HCV antibody positive, although correlation is >50% where both ALT is high and the Hepatitis B core antibody is positive.

The impact on our donor base will be moderate but not catastrophic, assuming that the 0.5% positivity level is confirmed. We will lose and have to replace 600

donors. There will be costs and operational problems associated with identifying them as HCV positive and they will have to be referred to Consultants specialising in liver work.

The cost to the BTS in the first year will be around £219,000 to £255,000.

I had read about this discovery before the date of this meeting.

The risks associated with HCV transmission at this time were primarily with the use of locally prepared blood and blood products. After the introduction of heat treatment, fractionated products including those from commercial sources did not appear to be at risk of transmitting viruses such as HIV and HCV.

Intramuscular products such as Anti-D had not been a risk, but I was aware of the issue of viral transmission in Ireland when the conventional fractionation regime had not been used for the manufacture of an intravenous Anti-D.

Other intravenous gammaglobulin preparations continued to present a risk for some time.

As with any testing regimen, there remained a risk of infection in locally prepared blood and blood components when the test did not detect the infection due to levels below the level of detectability by the test in use. The development of HBV tests over the years had clearly shown that each iteration of the test improved the sensitivity.

111. First Aware

See 110 above.

112. Relative Risks

The comparative risks of commercial and BPL-prepared products appeared to be related to the time at which viral inactivation steps were introduced by BPL compared to commercial manufacturers.

Prior to the introduction of viral inactivation, I was aware that commercial products were more likely to transmit viral infections. The source of plasma in the US used by the major fractionators was very significant, especially when compared to the source of plasma to BPL, from an entirely voluntary donor population.

113. Further Investigations

As far as I know, the Newcastle Centre did not carry out any specific investigations relative to HCV transmission.

114. Severity

This response is just a general note, it is not intended as a treatise on hepatitis.

Hepatitis A is typically a self-limiting disease, although acute and debilitating. Hepatitis B varies considerably, with risk of both acute disease and chronic carriage leading for example to cirrhosis.

In a note to staff at the Transfusion Centre (May 1991), reproduced in document NHBT0000192_042, I included the following:

> Last year a new virus was discovered which has been called Hepatitis C virus. A small number of apparently healthy individuals carry this virus and it can be transmitted through blood to the recipients of blood transfusions. The effect on the recipient varies considerably. In some cases it causes a mild non-specific illness which is only detectable by fairly sensitive laboratory tests, but in others it can cause a moderately severe bout of jaundice. The main problem is that in some people the infection continues to cause problems over many years and can eventually lead to serious liver failure or in rare cases Hepatic Carcinoma.

115. NANB report by Dr. Gunson

115(a) I do not recall seeing this.

I was aware of the issues of NANB hepatitis, the possibility of using surrogate testing (anti-HBc & ALT), and the poor correlation with clinical NANB hepatitis. I am not sure what the conclusion drawn from this Appendix is, other than that a further trial was warranted.

However the referenced article COLLINS J.D. et al. Prospective study of post-transfusion hepatitis after cardiac surgery in a British Centre, from 1983, seemed to give a better insight into the (then) contemporary acute NANB infection rate in the UK, at 2.4%.

115(b) I do not know if these figures were discussed by Transfusion Centre Directors. What was this appendix attached to and to whom was it distributed.

116. Other

I do not have anything else to add.

117. Impact on Screening

The screening of donors prior to donation followed the national guidelines as from time to time updated.

118. Decision Making Structures

I am not sure what is meant by this question. The Centre was aware of the risks associated with infection and followed the selection guidelines. Meetings with haematologists, particularly at hospital transfusion committees, discussed the need to limit transfusions, such as ending the practice of single unit 'top-ups'.

As seen in 'HIV_Window Risk', (WITN6935028), we did consider and look at risks associated with blood and blood components. The referenced document is an early draft of a talk I was preparing on transfusion risk. I do

not recall who the audience was to be and I do not have a copy of the completed set of overheads.

119. Advice to hospitals

All the haematologists that I dealt with were well aware of the issues and reduction in unnecessary transfusions was discussed.

Section 14: Reduction of risk of infections while at the Newcastle RTC

120. Donor Screening Processes

Donor screening was carried out at all sessions for both normal blood donations and plasmapheresis donations. No donation could take place without screening.

The clerical staff involved were all members of the Donor Panel department recruited for this role, rotating the session screening with other duties in the department.

Over my tenure as Director/Chief Executive there was a steady process of improving the information provided for the clerical staff to use. Ease of use was important. Documents needed to be clear and concise and lacking in ambiguity as well as being easy to use. The following extract from my letter to Dr. Gunson, then the Medical Director at the NBA, (document NHBT0007497) shows this approach:

> Re: Selection of Donors
>
> I know that you are now getting reasonably close to producing the Selection of Donors booklet. I thought you might like to see the version that we have introduced. The main aim in producing this booklet was to put all the possible information together into one alphabetic section. This means that staff are less likely to have to jump from one section of the book to another and to this end we have integrated conditions, vaccinations and country information into the same alphabetic list. In addition to this we have tried to repeat references where

possible so minimising the time required for session staff to find the relevant information.

121. High Risk Donors

Several of the documents referenced in this section (NHBT0118280, NHBT0072654 and NHBT0012061) show that the Centre took an active role in the way in which donors were screened. Discussions on risk and risk mitigation took place.

You may note that I am recorded as being involved in the process. The Selection of Donors booklet for use both in screening donors before they donated and making decisions post-donation, should new information become available, was formally authored by myself.

The introductory sections which describe the rationale and processes to be used, are shown in the Centre's Donor Selection Document, a draft version of which is seen in NHBT0007498.

Section 2 includes the following:

2. RATIONALE

There are two major considerations with regard to donating blood. These are:

(i) That all care should be taken to protect the voluntary donor from harm, and

(ii) That the blood or plasma collected should be safe for its intended use.

In addition to this it is the Policy of the NRBTS not to take donations of blood or plasma from donors unless at the time of collection, it is believed that the donation is suitable for use.

Note: NRBTS – Northern Region Blood Transfusion Service

122. Donor Information – written or oral

An 'AIDS' leaflet or an 'AIDS' poster were used at donor sessions. These changed over the years. The Newcastle Centre had no problems with providing this information. As required, prospective donors were referred to a doctor on the session for further discussion. At some stage, I don't have the exact date, all donors were asked if they had read the AIDS leaflet or poster.

My 1987 memo (NHBT0118280) indicates that donors were being asked to read an 'AIDS' leaflet or an 'AIDS' poster.

The memo includes these sentences:

> Donors who are in any AIDS risk group must not be bled. Where there is any doubt about the risk they should not be bled, but in either case, the potential donor should be sympathetically dealt with and arrangements made for an M.O. from the Centre to contact them, especially where doubt exists.
>
> The Session M.O. will discuss the matter further, in confidence. It may be difficult to ask donors about their sexual activities in the rather public circumstances of a blood donor session. The M.O. must, however, ensure that the donor has read and understood the AIDS leaflet (N.B.T.S. 1181 - Sept 86), or the AIDS poster.

In 1989 or 1990 we introduced a leaflet that was included with requests sent out to donors asking them to attend a blood donor session. This leaflet 'Donor Information Leaflet 1989_90', (WITN6935018), was commercially printed, and included the following section on AIDS:

> AIDS - (Acquired Immune Deficiency Syndrome)
>
> THESE PEOPLE MUST NOT GIVE BLOOD
>
> * Men and women who know they are infected with the AIDS virus or who have AIDS.
> * Men who have had sex with another man at any time since 1977
> * Men and women who have injected themselves with drugs at any time since 1977.
> * Men and women who have had sex at any time since 1977 with men or women living in African countries, except those on the Mediterranean.
> * Men and women who are prostitutes.

* Men and women who have had sex with anyone in these groups.

Sexual partners of haemophiliacs

From a draft for a 1992 document to be used at donor sessions, 'Health Questionnaire 1992 Draft', (WITN6935021), there is this:

Declaration by Donor:

I have read these questions and answered them fully to the best of my knowledge. I confirm that I am not in an AIDS risk group and that I have read the AIDS leaflet. I agree to my blood donation being tested for the AIDS / HIV virus and other infections. I understand that these tests are not infallible and I am not donating blood just to obtain a test. If a test is positive I know that I will be informed of the result.

In 1992 we updated the leaflet that was included with requests to attend donor sessions. From a draft for this leaflet 'Donor Information Leaflet 1992 Draft', (WITN6935022), the following was included:

F. AIDS and the HIV Virus

1. You will be asked if you have read the latest AIDS leaflet which will be available at the blood donor session. When a new version is produced it will be included with these invitations. Donating blood if you are in a risk group or if you think you have been at risk will endanger the lives of others. For confidential advice contact your Sexually Transmitted diseases clinic (see phone book) or contact Tyneside (091) .... or ask to speak to a Medical Officer, (in confidence) at the Transfusion Centre - Tyneside (091) 261 1711.

I do not have copies of either of the finished documents that these two drafts were used for.

123. Plasma Specification

123(a) This letter refers to draft specifications for plasma for fractionation. I doubt that it was introduced in the form extant at that time. The Centre had sound donor selection criteria based on the national

guidelines, likely excluding some of the idiosyncratic ones and applying more stringent rules in other areas. See 123(d) below.

123(b) Some of the statements in my letter of 3rd March 1992 (NHBT0000974) show where I felt that the draft guidelines were inappropriate, for example:

> For instance if one takes the requirement to exclude anybody who has or has had an auto-immune disorder (Chapter 2 paragraph 5.410) we will lose usable donations on the grounds of a risk that on theoretical grounds appears less than the risk of inducing GVHD from donations from individuals who have not had auto-immune disorders. I would incidentally challenge the concept that those who have had auto-immune disorders should not act as donors of local components on the same basis that the theory of auto-immunity would strongly suggest that there is no risk of inducing an auto-immune disorder in the recipient. I would have thought that the risk of inducing GVHD in recipients of other blood donations was equally great and is a risk that we are always prepared to accept in all but a minute percentage of our recipients who are provided with irradiated components.

I obviously cannot remember the details of a set of draft guidelines that I last saw thirty years ago and identify

> 'which rules were in your view myths or idiosyncratic, together with the reasons for your views on this'.

However, I have no doubt from the wording in my letter that that was my considered opinion at that time.

123(c) My letter includes only a couple of examples of the problems with the draft guidelines. To answer the question 'why the barred blood would be suitable for plasma fractionation' would require access to the original draft guidelines for a re-analysis of the specific selection criteria. As the guidelines were not, as far as I know, introduced in the form presented in the draft, the question is moot.

123(d) An obvious area where the rules applied in Newcastle differed from national guidelines, is the consideration of medications taken by prospective donors. The national guidelines had no scientific basis, whereas Newcastle used rules based on the individual drugs, their half-life and an assessment of risk to recipients. These, as mentioned in my answer to question 9, were developed in association with the Wolfson Unit, Northern Region Drug and Therapeutics Centre, at the University of Newcastle. The 'Rationale' and 'Method used to calculate interval', as used for donors on medication is shown in 'Donors on Medication', (WITN6935023).

This is part of the rationale described in the introductory section:

> The time intervals are based on the concept that there will be no significant risk to the recipient in transfusing a very small fraction of the average adult dose of any drug. For most drugs we have chosen this to be 1/100 of the therapeutic dose. To allow for a bigger safety margin where the side effects of drugs are not well known ie: drugs on 'special reporting' we have accepted only 1/1,000 of the therapeutic dose. Where anaphylaxis and other serious allergic phenomena have been associated with the drug the interval prescribed results in no more than 1/1,000,000 of an adult dose. This fraction has also been used for drugs which show aspirin cross-sensitivity eg some of the non-steroidal anti-inflammatory drugs which, even in small doses, have the potential to induce serious bronchospasm in those susceptible and it has also been used for drugs with teratogenic effects.

This shows that the Centre took donor selection seriously and any differences from national guidelines were made after due consideration and with considerable care.

124. Screening Kits

Documents NHBT0000075_065 and NHBT0091147 are not related to the question posed.

The purchasing of the test kits for infectious disease testing, prior to the move to the NBA, was carried out by staff at the Newcastle Transfusion Centre with the budget approved by the Northern RHA. When testing for Hepatitis C was required, the issue was discussed with the Northern RHA well in advance.

Information about the test and its background were shared with the RHA and they ensured that the appropriate funding was made available to the Centre. A July 1989 document (NHBT0000188_008) shows part of the preliminary discussion with the Northern RHA.

125. Funding

See above. As mentioned in NHBT0000075_068, the funding for HCV testing flowed through the hospital contract system, but was approved by the Northern RHA. The letter to Dr. Gunson (NHBT0000075_068) lets him know that there will be costs incurred elsewhere in the NHS as a result of introducing the test. Presumably in his position he could keep the DoH informed.

126. National Agreement

126(a) As far as I know there was no national purchasing extant at that time.

126(b) Not applicable

126(c) The main issue with a national contract arrangement would be that the approach could have resulted in a move away from the integrated system used in Newcastle. This would have had a significant impact on the automated transfer of validated results to our main computer system with associated changes in staffing, and

associated staff training and audit. I could go on. Suffice it to say that when you have an effective and cost effective 'system' in place you do not want to be held hostage to 'best cost' test kit that results in an overall higher cost.

126(d) Purchasing test kits and associated equipment was a joint task including the Operations Manager, the Finance Manager and myself with input from senior laboratory staff and the Medical Director.

126(e) The comments under 126(c) above cover this issue.

127. Key Factors in choosing a kit

Apart from the obvious performance data, such as sensitivity, specificity and test failure rates, the ease of use, integration with existing systems, staff training, equipment maintenance, mean time between failures, equipment repair response times, maintenance and auditability all play a part.

Multiple tests run on the same equipment is also of note as it provides short term backup/resilience.

128. Influence

128(a) I cannot comment on any influence companies may have had on purchasing by others in the wider Blood Transfusion Service. In Newcastle we made the decision to move to one company's system based on criteria, as discussed in 127 above.

128(b) The date for starting screening was based on a decision to test and the availability of tests capable of meeting the screening requirements.

129. Post introduction influence

I cannot see any reason why a manufacturer of test equipment and test kits would not provide advice on the use of the system after its introduction. I

would have been unhappy if the manufacturer just walked away and provided no further support and advice. The company is likely to have multiple users in different countries and they are in a position to share what others have learnt. Newcastle often hosted visitors from other locales at the request of a supplier, to demonstrate their system in use and exchange information.

130. Hepatitis B testing

I have no knowledge about this.

As to the question:

> Was the introduction of testing simultaneous across the NBTS?

You may wish to refer to a statement by Dr. Gunson in NHBT0088808:

> ... a Department of Health Advisory Committee on Testing for the Hepatitis-associated Antigen recommended in July 1971 that routine testing of blood donations should be undertaken. Despite the RTDs agreeing that the introduction should be undertaken on a nationwide basis, there were considerable difficulties. Shortage of test kits meant that preference had to be given to the screening of donations used in renal dialysis units where several deaths had occurred from hepatitis B and to a panel of donors supplying plasma for the preparation of fibrinogen, a fractionated plasma product known to transmit hepatitis B. Routine screening of blood donations was introduced during the course of 1972 and it was not until December 1972 that all blood was being tested.

131. Electrophoretic HBV testing

This was long before I was with the Transfusion Centre. I have no information about these issues.

132. Introduction of HIV testing

I was not working in the Transfusion Centre when HIV testing started. I am sure that there are records which show the start of testing, such as data on tests undertaken, sent to the National Directorate.

A new transfusion centre was under construction at about the time of the introduction of HIV testing. My understanding was that a post-handover contract was used to modify part of the new building to provide additional space for the HIV testing.

133. Implementation of HIV testing.

133(a) This has already been discussed.

133(b) As noted above, I was not working in the Centre when testing started, so I am unable to provide any further information.

133(c) HIV positive donations, any components and test samples were sealed and autoclaved before disposal.

The management of the donor has already been discussed.

133(d) There were no untoward impacts on the Centre as far as I could tell when I came back to work at the Centre. The testing appears to have been fully funded by the Northern RHA, as well as funding the building modifications.

134. Surrogate testing for NANB

I do not recall this specific report. However I was aware that surrogate testing was not being recommended.

I did consider that surrogate testing might have reduced risk, but the use of surrogate testing is difficult in that there was no clear link between test results and infectivity. I was not opposed to additional testing , but it was not being put forward for use in the UK and I acquiesced in this decision given the weight of expertise in the Transfusion Service on the topic.

135. Maximum Safety.

To decide to not introduce surrogate testing given the information on the reduction in non-A, non-B hepatitis in recipients was from my limited perspective a decision not to apply a 'maximum safety' ethos. I think that a substantive trial in the UK would have provided a better basis on which to make a decision. Data from other countries did not necessarily apply in the UK and from what I have seen, US data was also not current in terms of donor screening and also due to the different blood collection arrangements in the US.

This was not a simple decision to make.

136. Decisions of the ACTTD and ACVSB.

I was not aware of this report. Reading it now I can see that introducing surrogate testing was a moot point at that date (late 1989) now that HCV had been identified, and specific testing would likely start soon.

137. Surrogate Testing in Newcastle.

The document referenced (NHBT0000077_073) clearly states that surrogate testing was not being performed in Newcastle. At the date of this letter, 22 October 1991 Newcastle had already been testing for HCV for over six months, and as such surrogate testing was no longer an issue.

138. If surrogate testing was introduced

As noted in 137 above, Newcastle did not undertake surrogate testing.

The Centre never started surrogate testing and as such there were no

'circumstances in which the Newcastle RTC stopped surrogate testing'.

139. ALT Testing of plasma obtained by plasmapheresis

The information contained in the question answers the question.

140. Anti-HBc testing.

140(a) I supported the introduction of anti-HBc testing because there was clear indication that some donations which were negative by the existing HBV test were indeed capable of transmitting hepatitis B.

This test had a clear impact on safety and a direct link with disease in the donor which could then be managed/treated.

140(b) I think that there was support for introducing this test. I do not recall significant objections, but I do not have documentation to support my view.

140(c) I cannot speak to the thought processes of the DoH.

In May 1993 I spoke to Dr. Gunson about the start date for the HB-core test and in an internal memorandum 'HepB core memorandum', (WITN6935033), I included this:

> As usual it looks as if the National Directorate (now the NBA) and the Department of Health are being incredibly slow in their deliberations and of course should have introduced this test earlier this year, given the information they had available from the Liverpool study.

140(d) As per 140(a). above, it would have reduced the incidence of transfusion-transmitted hepatitis B.

141. Introducing anti-HBc.

I cannot comment on how the DoH came to their conclusions. I do not see any evidence that the Blood Transfusion Service 'balanced' anything with the DoH.

Dr. Gunson as the National Director had already indicated that testing would go ahead and had coordinated a trial. See NHBT0018413.

142. ACVSB Agreement.

In the minutes of the November 1990 meeting of the ACVSB (NHBT0000073_018) the statement:

> The Chairman stressed the importance of a common date of introduction throughout the UK

is presented without any background information. There is nothing in the document that indicates why the Chairman (Dr. J Metters) came to this conclusion.

I note these statements in the document

10. 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.

18. The Chairman summed up the discussion by saying that there was agreement that the UK should introduce hepatitis C testing as soon as practicable.

21. [Dr. Gunson] reported that some centres had asked for a 6 month period in which to set up testing. Dr. Gunson himself thought this to be excessive, but he said he would need to consult with other Directors first.

This suggests some disconnect in the thinking ... as soon as practicable ... but only if all together.

I also note that Dr. Gunson prepared a paper in October 1989 for the UK Advisory Committee on Transfusion Transmitted Diseases (NHBT0000188_072) primarily reporting on the first International Meeting on the Hepatitis C virus, held in Rome in September of that year, in which, inter alia, he states:

> 7. RECOMMENDATIONS
>
> 7.1 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 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.

In Dr. Gunson's witness statement NHBT0000025_001 he comments on issues of a common start date:

> When HBsAg was introduced during the 1970s there was a period of over one year before all RTCs were testing all donations. This meant that patients in some regions had the advantage of receiving tested blood whilst others did not. This was clearly unacceptable and when the next test was introduced (anti-HIV) considerable efforts were made to ensure that the test was introduced simultaneously throughout the UK.

In my 1989 witness statement shown in TYWE0000067 I included this comment:

> I believe that there were meetings attended by the Regional Transfusion Service Directors and that as a result of arguments advanced by Dr. Gunson at Manchester, testing for the HIV infection was introduced on a uniform basis in October 1985. Dr. Gunson in particular felt that the testing should commence at a particular point in time, although some Regional Transfusion Centres may have been in a position to institute testing for the HIV infection at an earlier date.

These suggests that it was Dr. Gunson who wanted simultaneous introduction of the tests.

As I was responsible for starting HCV testing in Newcastle earlier than other Transfusion Centres, I clearly do not agree with the minute that refers to a common date of introduction throughout the UK.

The argument put forward by Dr. Gunson (referring to HBV testing in the 1970s) that 'some regions had the advantage of receiving tested blood whilst others did not' sounds like a reason for a common start date, but the alternative is that *nobody* gets tested blood until the last Centre is ready to

start testing on a delayed common start date, denying many individuals the additional protection in the interim.

My views have not changed since then. I did not of course see this document, and at the time, only received filtered information from Dr. Gunson.

If I had seen document NHBT0000073_018, I might have considered starting testing earlier than we did. It would have altered how I viewed Dr. Gunson's memo of 22nd January 1991, (NHBT0000076_006). He made no mention that the ACVSB had agreed at a meeting in November 1990 that it was important to commence routine anti-HCV testing 'as soon as practicable'.

143. First generation Test and Specificity

The comments in document PRSE0003170, which report on a study using first generation tests, show the impact of the lack of specificity in that it was estimated that if extrapolated to the whole country between 9,000 and 10,000 donations would be 'repeat positive' and would be destroyed despite any confirmatory test results, with only around 1,250 of these being confirmed as HCV positive.

Thus the first generation tests had some issues with specificity.

From the 1st generation test study conducted in three Centres in September 1990, the annual equivalent loss for Newcastle would have been of the order of 500. The number of true positives found would have been about 80, less than the about 100 that were found when testing with the 2nd generation test in its first year in use. The difference is presumably due to a lack of sensitivity. (Numbers have been drawn from the limited study results shown in PRSE0003170 and freely rounded).

The lack of specificity meant that about 400 or so donors would have tested positive, but were not infected – a lack of specificity.

I don't recall when the RIBA II confirmatory assay became available, but it was used to assess reactive results from the September 1990 1st generation study as reported in February 1991 (PRSE0003170) and 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.

144. Preparedness for HCV Testing

Although formal notification of the introduction of testing appears to have been in January 1991, as seen in document NHBT0000076_006, it was well known that HCV testing was highly likely to be introduced. The Newcastle Transfusion Centre had already obtained funding for 1991/92, discussions starting in 1989.

As mentioned before, Newcastle had decided to introduce a single test system for most infectious disease tests. We had recognized that this approach gave flexibility and capacity to our testing arrangements.

Adding an additional test was relatively simple and did not require additional staffing.

We could have introduced testing earlier, based on our laboratory status, staffing and expertise.

I am not in a position to comment on the issues faced by other Transfusion Centres.

145. Proposed Introduction Date.

Dr. Gunson notes in document NHBT0000191_077 of 15th February, that an agreed date for commencement 'has emerged', this being 1st July 1991.

In my note of 6th February shown in NHBT0000191_060, I refer to Dr. Gunson looking for all red cells available for issue to be HCV negative by 30th June 1991. This pre-dates the NHBT0000191_077 document referred to above and of course required a much earlier start date than 1st July.

Without obtaining a full timeline of documents on this topic, I can recall that starting dates changed, and always to a later date. My general assumption was that when a starting date was proposed, it was the date to start testing and not the date at which all red cells for issue would be negative.

I note the further change to a start date of 1st September 1991 as seen in the 3rd April 1991 letter from Dr. Gunson (NHBT0000073_065):

> 'It has not yet been possible to commence the evaluation using production batches of the second generation tests referred to above and one of these will not be available until later this month. It is undoubtedly in our interest that this evaluation takes place. However, to complete this study and become operational by 1st July 1991 is too tight a schedule. It is difficult to state precisely a revised date, but I think we should aim to commence routine screening for anti-HCV by 1st September 1991.'

This indicates that Dr. Gunson now supports the further evaluation and was prepared to put back the start of testing to September of that year or possibly later. I note the phrasing

> '… I think we should aim to commence …'

At the time, I was concerned that the start date would be postponed beyond the first of September, as I noted in a letter to Dr. Gunson (NHBT0000076_009):

> '… but I could not take the risk of being forced to hold off testing until at least September and possibly later.'

His comment

> 'It is undoubtedly in our interest that this evaluation takes place'

should also be viewed alongside his comments in 1999 (NHBT0088807):

> With the benefit of hindsight I have indicated that we should have introduced routine testing without the second evaluation or at least, tested the 10,000 or so frozen donations whilst using the test routinely. I think we will be criticised severely for not; doing this, since there were many countries throughout the world where the second generation tests had to directly supersede the use of first generation tests. By April 1991, only Denmark and some centres in the Netherlands and Italy were not screening routinely.

I have no idea how other Centres interpreted these dates.

146. Further Test Kit Evaluation

146(a) I do not know why the ACVSB asked for further evaluation. My understanding was that the second generation tests showed a considerable improvement in specificity and no loss in sensitivity.

In the ACVSB minutes shown in PRSE0002280, there is the following:

> 7 The Chairman summed up the view of the Committee following discussion:-
>
> the bank of specimens from the original 10,000 should be kept in appropriate form in order to evaluate the 2nd generation tests, as well as any other tests as they became available. … Any new test should be evaluated against the full 10,000 specimens to ensure it was at least as good as the tests already evaluated.

I note that in document NHBT0000062_039, a memo that appears to be between individuals at the Department of Health, the author questions the value of the study and notes that the sub-group of the ACVSB did not recommend the further evaluation in the form that the full committee proposed:

> 2. The second round HCV test-kit trial/evaluation which ACVSB asked for will cost up to £117,000 from MDD's 1991/92 evaluation budget. I

understand that the sub-group of ACVSB which worked up the proposal recommended a more modest project concentrated on the 3,500 archived samples from the North London NBTS Centre but that the full group felt that the more extensive study at three centres was required.

3. I gather that Dr. Gunson, who was not present at ACVSB on 25 February, has telephoned Mr Fuller to say that he doubts whether the Newcastle and Glasgow Centres have the laboratory capability to carry out the additional work now proposed. I understand also that Dr. Rejman is unsympathetic to Dr. Gunson's view on this. However, I think you should be aware that Dr. Gunson has raised this point as it seems to underline the need to look very carefully at what ACVSB has advised to be sure that an evaluation on the scale proposed is both necessary and practicable.

This suggests that there was doubt about the need for a further study using new donor samples, with its long lead time and longer duration, compared to re-testing existing stored samples.

In 1999, see NHBT0088808, Dr. Gunson expressed his view that a second generation test study in this format was not necessary and it was not how many countries proceeded:

'I noted that you [Mr. Simon Pearl with Davies Arnold Cooper, Solicitors] asked John Barbara to prepare a paper on his views why the assessment of the second generation tests could not have been undertaken whilst the test was being used routinely. This was how this test was evaluated in most countries and it is my view that we could have done this also. The extended trial was a damage limitation exercise ...'

146(b) In early 1991, prior to Newcastle starting HCV testing, I did not see the need for a further evaluation. We would have started testing with the first generation test anyway. The Newcastle Centre's plan was to start testing on 1st April 1991 using the Abbott first generation test.

Thus not starting testing but running a trial on the more effective second generation tests was illogical.

146(c) My comments shown in NHBT0000074_026 and NHBT0000192_028 were purely speculation.

My speculation in NHBT0000074_026 was based on this paragraph in the letter to me from Dr. Contreras (Director, North London Blood Transfusion Service), dated 3rd May 1991, in NHBT0000192_009:

> Moreover a national approach might well have prompted the Department of Health to provide appropriate funding for testing with all its ramifications such as confirmatory assays, counselling and donor referral. Now, I can see no hope of presenting a united front in pursuit of central funding.

147. Commencement of Testing in Newcastle

There were many comments on the start of testing in Newcastle in April 1991, as shown in the referenced documents. Some of these letters I had not seen before as they were not addressed or copied to me.

At the time, I and the Newcastle Centre were ready to start testing on 1st April 1991. A delay until July dismayed me, and a proposed delay until about 1st September was unacceptable. We all knew that there were infectious donations in the system that were being transfused to patients and we had the means to stop that.

As alluded to in 'A joint statement by J. A. J. Barbara and H. H. Gunson' NHBT0088813_002, that he [Dr. Lloyd]

> ' ...thought that the National Director would attempt to talk him out of doing so and this is why he informed him after the event.'

is not quite the situation as I saw it. I believed that an *instruction* not to test might be issued through the DoH to the Northern RHA, initiated by Dr. Gunson.

In my letter of 24th June 1991 to Dr. Gunson (NHBT0000076_009), I included this:

> Nevertheless I would like to apologise to you for not informing you of my intentions earlier. I appreciated at the time that it would give you problems, but I could not take the risk of being forced to hold off testing until at least September and possibly later. This would have resulted in the transmission of Hepatitis C to many patients in this Region, something that was avoidable.

In the letter to Transfusion Centre Directors referenced in point f, (NHBT0000192_024), Dr. Gunson includes a press briefing note ('… not intended to be issued to the press but can be used as a brief to answer press queries') which inter alia states:

> Line To Take …but it should be noted that Hepatitis C is normally only a mild infection …'

is remarkable as a justification for delaying testing, especially considering that Dr. Gunson had recommended the introduction of testing as far back as October 1989 (NHBT0000188_072) and that the Chairman of the ACVSB in its November 1990 meeting (NHBT0000073_018) had summed up the discussion by saying:

> that there was agreement that the UK should introduce hepatitis C testing as soon as practicable.

Some of the comments are clearly nonsense, such as this in the letter from Dr. Ala, the Director of the Transfusion Centre in Birmingham (NHBT0000074_020):

> '…nor is there any evidence of HCV prevalence sufficient to justify your precipitate decision on epidemiological and scientific grounds.'

This is a strange criticism to throw at Newcastle's decision to start testing, given that Dr. Ala had stated in response to Dr. Gunson's earlier request, that they would be able to start testing by April [1991]. See Dr. Gunson's witness statement (NHBT0000026_009) item 85, re: Birmingham.

Dr. Ala had not, as far as has been shown, disputed the need for HCV testing as advised by the ACVSB and the National Director, Dr. Gunson.

I also note this from Dr. Gunson:

> Your actions were taken "despite the agreed policy by the ACVSB that screening should start simultaneously in all the RTCs in the UK."

However minutes from the ACVSB include this statement:

> 10. 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. [my emphasis]

In an internal DoH memo from JC Dobson (DHSC0003620_001), the issue of starting 'as soon as practicable' seems to override the concept of 'a common start date':

> Ministers decided, on a recommendation by the Advisory Committee on the Virological Safety of Blood (ACVSB), that all donated blood should be screened for Hepatitis C antibody as soon as practicable. It was intended that all regions would start testing on a common start date.

The issue of starting as soon as practicable must take priority over an 'all at the same time' philosophy. I have not seen anything that shows that not starting at the same time had a significant detrimental effect on the quality of health care provided by the NHS.

Dr. Gunson also says this about the 2nd generation tests in his 9th May memorandum (NHBT0000192_024):

> ' … we have only the manufacturer's opinion of their efficacy.

However, he was aware by 6th February 1991 of the efficacy of the Abbott 2nd generation test. My memorandum to the head of our infectious disease testing department (NHBT0000191_060) refers to Dr. Gunson mentioning the Glasgow study and its performance.

Some of the content of this group of documents from other Transfusion Centre Directors seem to display 'righteous indignation', but little or nothing concerning the recipients of infected donations.

Regarding point e in the question,

> The introduction of testing undermined public confidence by creating inconsistencies in testing and giving the impression that blood was less safe" in certain areas

is a somewhat specious argument as the blood across the country was going to be less safe as a result of the delays, just that the general public wouldn't know it.

Regarding point c in the question:

> Your actions would have implications for your colleagues, and "caused problems in Scotland."

If problems were caused for Scotland it was more because of the delayed start perpetrated by the National Directorate for England and Wales, as I understand that the service in Scotland was already funded for a start date in April. Indeed, from the SNBTS, it was only Dr. Cash who complained about Newcastle breaking ranks.

I also note that the Bio Products Laboratory did not complain about Newcastle starting testing earlier than the rest of England and Wales as seen in the letter from Dr. Richard Lane, 'Lane BPL Reply', (WITN6935031).

'Have your views changed since?'

No, my views have not changed on the fundamental issue of starting testing when we did. I have however pondered over the issues on occasions over the subsequent years and as I stated in my memo of 18 June 1991 which summed up my thoughts from a Directors meeting that month (NHBT0000192_092), my only regret is that I did not start testing earlier:

> At the end of that meeting I felt confident that as a Centre we had made the right decision to proceed with Hepatitis C testing when we did. My only regret is that we didn't introduce it 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.

148. Legal Liability

I am not a lawyer, but my view was and remains, that if I as the Transfusion Centre Director knew that the Centre had the ability to test, had the staff and equipment to test and that funding had been provided, then not testing was an indefensible position.

It goes without saying that not testing under these circumstances resulted in patients becoming infected with the hepatitis C virus.

As to how my views differed from that of other Centre Directors and Dr. Gunson, it is clear from the responses from many of them that they believed that having everyone start at the same time was a protection against liability.

149. Extended Study

At the time I felt that calling the introduction of testing 'an extended test' rather than what it was – the introduction of routine testing, was a face saving exercise.

I had not previously seen Dr. Gunson's comments in a letter to Dr. Contreras (NHBT0000192_051)

> The second evaluation, about which I wrote last week, is a damage limitation exercise following Huw Lloyd's decision to institute testing unilaterally.

I cannot say what was in the mind of Dr. Gunson when organizing this 'trial'. Additional data on the second generation tests was valuable, although if several centres had started testing at that time, the data would have been available anyway. Confirmatory testing using PCR would still have been required as part of a study.

I once again note Dr. Gunson's comment in a letter he wrote to Davies Arnold Cooper, Solicitors in February 1999 (NHBT0088808):

> The extended trial was a damage limitation exercise and, as was commented during our recent meeting, if it had been a proper trial it should have ceased at its conclusion.

This again supports my view at the time that the trial as it was structured, painting Newcastle's testing as an 'extended trial' was a charade and a face saving exercise.

In the same document I note this paragraph by Dr. Gunson:

> I am uncertain whether it will be possible to demonstrate that the decision taken by Newcastle was maverick and premature, but if you could extract the responses referred to above from the NBA papers and send them to me I will see what I can put forward.

I do not know if Dr. Gunson succeeded in his attempt.

150. Further introduction

As a number of Centres had stated in response to an enquiry from Dr. Gunson, that they could start testing in April, May or June of 1991 then a wider-spread implementation of testing was clearly possible.

The delay until September seems to indicate that one or more Centres were not able to start testing until then.

It might have been possible to manage the few outliers by having their samples tested at another Centre, perhaps utilizing a night shift, so enabling at least a June start date.

151. Second Round Evaluation

I do not recall that the outcome of the evaluation resulted in any changes in how we performed the second generation HCV testing.

Also in 1999, writing to Dr. John Barbara, (see NHBT0088807) Dr. Gunson includes the following:

> You may have heard from Pat that Simon Pearl [with Davies Arnold Cooper, Solicitors] has asked me to expand my report with respect to Newcastle's unilateral decision to introduce anti-HCV tests in April 1991 to demonstrate that this was maverick and premature.
>
> ...
>
> With the benefit of hindsight I have indicated that we should have introduced routine testing without the second evaluation or at least, tested the 10,000 or so frozen donations whilst using the test routinely. I think we will be criticised severely for not doing this, since there were many countries throughout the world where the second generation tests had to directly supersede the use of first generation tests. By April 1991, only Denmark; and some centres in the Netherlands and Italy were not screening routinely.

From this I conclude that the second round evaluation was not a requirement for introducing second generation HCV testing, and made no difference to the 'outcomes for testing' at Transfusion Centres.

152. Organizational Issues

The delay in introducing HCV testing (first or second generation) was of course organizational. As noted by Dr. Gunson, in 1999 (NHBT0088807):

> By April 1991, only Denmark; and some centres in the Netherlands and Italy were not screening routinely.

I assume that this referred to EEC countries. Thus if other European countries could implement the test, then the UK's failure can only be organizational in nature.

I again refer to the ACVSB meeting report of 21 November 1990:

> 10. 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. [my emphasis]

153. Manchester PHLS Study

I do not see any reason to try and reanalyze the PHLS(M) study. Suffice it to say I discussed it with scientific staff in the Newcastle Centre, and it was clear that this study was seriously flawed.

My letter of 9th August 1991, NHBT0000192_139, includes some of the issues with the study and a note I made for myself at the time 'Comments on Manchester PHLS Study', (WITN6935030) contains more complete information.

As far as I recall, it had no impact on confirmatory testing in Newcastle.

154. Earliest Date of Implementation

154(a) Earliest Start Date by Newcastle.

This is hard to say. A lot would have depended on when we started planning. We were in a position to start testing before the second generation tests became available.

As we did not attempt to get funding in place prior to the 1991 fiscal year, any earlier implementation would have been more difficult. However, given the attitude of Senior staff at the Northern RHA, an earlier start date in 1991 mighty have been possible.

With hindsight, had Dr. Gunson transmitted the November 1990 recommendation of the ACVSB to start testing as soon as practical, then the RHA might have been prepared to provide interim funding to cover a period from say January 1991 to the start of the fiscal year in April. This is of course supposition. Without funding approval we could not have started testing before 1st April 1991.

I also note that, although I was not party to the discussions at the ACVSB and their minutes were not circulated, that the introduction of HCV testing required ministerial approval.

Dr. Gunson in his statement shown in NHBT0000026_009 states the following:

> 81 It was effectively at the meeting of 21st November 1990 that a final decision was made to proceed with HCV testing, although that decision had to be confirmed by Ministers, and I was not informed that approval had been received until shortly before 22nd January 1991. The issues thereafter related to implementation.

From this it would appear that a start date earlier than January 1991 would not have been possible (although I did not know this at the time).

With an earlier start date, some of the mechanics of implementation would have taken longer – computer system integration and the like. (By April 1991 we had ironed-out most of these issues).

154(b) As to simultaneous implementation across the UK, it is necessary to consider that Dr. Gunson in his role as National Director, already was unhappy with the slow implementation at certain Centres, but was unable to bring the coordinated start to a date earlier than 1st September 1991.

See also my answer in 150 above.

155. International Start Date Comparisons

In replying to this I would only be reiterating data provided by Dr. Gunson.

156. Impact of Testing.

156(a) There was no impact on donor screening or donation testing. The HCV test was directly integrated into the existing system.

156(b) As far as I remember (NHBT0097466_006 does not appear to be relevant), there was a cut-off date after the start of testing when all units of red cells would be guaranteed negative. All platelets would have been negative before this date. I seem to recall that we destroyed a small number of red cell units that were near expiry date (typically low demand blood groups). I am not sure now how we handled frozen plasma, although I have a vague recollection that we ran down stocks of locally held FFP and Cryo. prior to our planned start date.

156(c) Positive donations and associated samples were sealed and autoclaved before being disposed of.

Positive donors were permanently excluded from future donation.

A consultant haematologist was responsible for donor and donation follow up, and as previously discussed there were delays in this process in the first year of testing.

The Centre would have had a written policy for the procedures, but I do not have copies of those documents.

157. Viral Inactivated Products.

I was not aware of the situation in the 1970's and early 1980's.

I note that the Transfusion Centre acted as a passive holding facility for factor concentrates en-route to the Haemophilia Centre.

158. Heat treated products.

I do not recall the exact date on which heat treated products became available from BPL. I had no involvement with commercial equivalents.

159. 1992-93 Business Plan – Plasma Product Overview

This was a high-level overview as part of the business plan and was aimed at the RHA management.

I do not have the data on which I based some of these comments.

It was obviously my view at the time.

My comment that 'the highest reasonable standards were either not aspired to or adhered to' was drawn from the situation in France and not the United Kingdom.

160. Autologous Transfusion Program.

I have not been involved with an autologous transfusion program for around 25 years and as such my expertise is severely limited. To attempt to provide a risk benefit report would not be appropriate for me.

The Newcastle Centre did run small autologous programs. The report shown in NHBT0009710 from November 1991, shows that it was available to patients from 6 or 7 hospitals.

In 1993, in a draft of a contract document for Autologous Transfusion Services, shown in 'AutologousTransfusionContract1993-94', (WITN6935024), nine hospitals are shown as having used the Transfusion Centre's Autologous program during 1992/93. The programs were still extant when I left the service in 1995. I do not recall the years in which they started.

161. Change in Autologous Transfusion Practices 1988-1993

I am not in a position to comment on this. My involvement in the autologous programs in Newcastle was limited.

There was an increase in autologous blood use in the Region over these years. I don't have numbers, but it remained a small program.

162. Infected donations contaminating plasma pools

During my tenure at the Newcastle Transfusion Centre, an extensive quality assurance program was developed, as shown by the Centre's accreditation to BS 5750: Part 2:1987 which later became BS EN ISO 9002 1994.

As shown in 'Quality Systems Policy', (WITN6935025), extracted from the Centre's Quality Policy Manual, this was the policy as it stood in November 1993:

> 4.1.1 Quality Policy
>
> The Northern Region Blood Transfusion Service provides a quality assured and effective service to meet the needs of all patients within our Region. Quality principles are pursued at every stage.
>
> Our care and treatment of the voluntary unremunerated Donor is designed to make the experience satisfying and positive, both to reinforce the Donor's wish to help others and to encourage regular donation.
>
> From the selection of Donors, through collection, processing and testing to the final despatch of Blood and Blood components, a team approach has been adopted which ensures that every member of staff is aware of the dependence of each stage on all the others for the achievement of the correct standards.
>
> Management responsibilities are clearly defined, materials and equipment are purchased from reliable suppliers to specified standards. Staff are suitably qualified, trained and instructed in the work to be done and the quality achieved is closely monitored.

The blood and blood components which we provide are produced to a standard which satisfies the highest statutory, professional and legislative requirements, both to ensure the safety of the patient and to obtain the maximum benefit from each donation of blood.

Quality Systems comply with requirements of BS 5750: Part 2:1987, with full details documented in the Quality Systems Manual. A Management Representative has the authority to ensure the implementation and maintenance of those systems.

A personal commitment is required from all staff to implement and maintain the policy and procedures documented in the Quality Systems Manual.

Dr. Huw L. Lloyd MB, BS, MRCPath

Chief Executive

Date : 26th November 1993

The Centre was audited by the British Standards Institute against the requirements of BS5750 part 2 (later ISO 9002), and the centre was audited by the MCA against the relevant requirements of the Medicines Act 1968.

With regards to plasma destined for BPL and inclusion in plasma pools, our processes and our quality assured programs guarded against any possibility of infectious product entering the system.

There remained the possibility of plasma from apparently healthy donors carrying an infectious agent that was either not screened for or was not detected by the existing tests being dispatched to BPL.

As to discrepancies in donations intended to be sent compared to those actually sent and received at BPL (NHBT0001549), each individual pack of plasma for BPL was barcode scanned and the product packed in a barcode labelled box. The system limited box inventories to a specific number, 20 I think, refusing to scan additional packs if the limit was exceeded. Box inventories were derived from the computer monitored process. Prior to April 1991, the system was computerized but 'stand-alone' with records

stored on paper and after this date all records were held on computerized media integrated with other parts of the operation. Thus it is highly unlikely that the Newcastle Centre dispatched plasma units to BPL, which it had not intended to dispatch.

163. Tracing a Contaminated Donation

From what I see in the documentation, the Newcastle Centre was not the source of any contaminating units.

164. Recall of Infected blood and Products.

The Centre had procedures, clearly described in Standard Operating Procedures, for the withdrawal of a unit. It is highly unlikely that this would be the withdrawal of an infected unit. Withdrawals were typically based on post-donation information from the donor.

165. Directed Donations.

I do not recall any other occasion when 'directed' donation was proposed.

166. Guidance To Hospitals / Haemophilia Centres

The question:

> 'were you ever involved in providing guidance to hospitals and/or haemophilia centres in the Northern region on the efficient and appropriate use of blood and/or blood products'

is so extraordinarily wide that I would need pages to answer it. As part of the role of a Consultant Haematologist and as the Director, I discussed transfusion matters/provided guidance on a regular basis over many years.

I could not see the relevance of SBTS0000096_076 to this question.

167. All other steps or actions

This is an impossible question to answer.

The Centre continuously worked to improve its practices, and the safety of the blood and products prepared was an essential part of this, not only safety from an infection point of view but safety from the correct preparation of the blood and products, including their labelling, storage and transportation.

Being the first Transfusion Service to achieve accreditation to ISO9002 or its UK equivalent BS5750 part 2 attests to this.

From memory, the last MCA audit of the Centre before I left, had difficulty finding anything to report. I recall that the colour of the copper sulphate solution used for haemoglobin screening at sessions was questioned. However our in-house data showed that we did not have a problem. A review of this inspection report would help, but I do not have a copy of it and it was not supplied as a document for me, by the Inquiry.

168. Safety and Cost

I always felt that the Northern Regional Health Authority supported the ongoing development of the Centre and the provision of safe products.

169. RTC Consensus and safety.

I valued the views of other Centres, but did not feel constrained by those views. The management and operation of the Northern Region Transfusion Service was not a management by Consensus.

The delay in the introduction of HCV testing was a consensus problem.

170. Reliance on Other Bodies.

Statutory bodies provided standards to abide by and committees provided guidance. As a Centre we recognized what were statutory requirements and did our best to meet them. Guidance from committees etc. were just that;

guidance. Some guidance was not appropriate other was of considerable value.

It was ultimately my decision taken after discussions with other senior staff as to what we did and how we did it. We did not decide to ignore or bypass statutory requirements.

In our Quality Policy Manual, the primary external reference documents were listed as shown in 'ReferenceDocuments.pdf', (WITN6935026). It was the Quality Systems department's responsibility to ensure that the latest versions of these documents were available and that when a new version was issued, all prior versions were removed from circulation. Distribution lists for these documents were maintained.

2. LIST OF REFERENCE DOCUMENTS

2.1 Department of Health "Guidelines for the Blood Transfusion Service". (Current version).

2.2 The Rules Governing Medicinal Products in the European Community. Volume IV Guide to Good Manufacturing Practice for Medicinal Products. Commission of the European Communities, Strasbourg.

2.3 The Medicines Act 1968 (HMSO).

2.4 Guidelines for Autologous Transfusion (Current version).

2.5 British National Formulary (Current version).

2.6 Guide for the Preparation, Use and Quality Assurance of Blood Components - Council of Europe, Strasbourg 1992.

171. Maximum benefit at minimal cost.

I was not aware of their comments at the time. A move from maximum benefit at minimum cost to one where the risk of injury to patients becomes more important, has been happening for years. This is what our society expects.

172. Shift.

A shift from one paradigm to another was not a single step. You cannot say that the Transfusion Service as a whole was subject to a policy decision on this.

Shifts like this should be initiated by the senior management of an organization, perhaps this would have been a role that the National Directorate could have taken on.

In Newcastle, early in my tenure, we made a lot of changes, starting to sit back and think that the work was done, the Laboratory Manager said 'we have to recognize that change will be our new normal' (I paraphrase his words).

Section 15: Look back programmes at the Newcastle RTC

173. HIV Look Back Setup

I was not involved in setting up this program.

174. HIV Look Back Implementation

By the time of my involvement, this was a rare occurrence and I do not now recall the details. Funding was part of the Centre's normal operating budget.

175. HCV Look Back Setup

I would have been involved in this. However, I do not recall starting such a program.

The Centre's Standard Operating Procedures should be reviewed to see if look-back was implemented.

If we did not implement look back, I cannot explain why we did not.

I note that in NHBT0000073_018, Minutes of the 21st November 1990 meeting of the AVSB there is a note about look-back:

COUNSELLING OF HCV POSITIVE DONORS (ACVSB 8/6)

20. Dr. Gunson introduced his paper and said that the UKBTS Advisory Committee on Transfusion Transmitted Diseases would be meeting to discuss the problems of counselling positive donors.

21. In addition two further aspects would be considered:

a. the question of look-back in relation to routine screening

b. the date of introduction.

I also note that in PRSE0002280, Minutes of the 25 February 1991 meeting of the AVSB, they specifically recommend against HCV look-back:

14 The Committee 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.

The minutes of subsequent meetings may provide additional information on the look-back situation and national advice.

176. HCV Look Back Implementation

The handling of clinical issues associated with HCV was the responsibility of a Consultant Haematologist, Dr. Anne Collins. However it would not have been her responsibility to decide if look-back was to be implemented.

Funding for work at the Centre, related to HCV was included in the operating budget, additional funding having been allocated by the Northern RHA, and passed through the hospital budgets.

177. Other Look Back

I do not recall any other look back program.

178. Tracking Donors

In the case that a donor potentially implicated in the transmission of an infection, i.e. the donor's donation or part of it was transfused to someone who later developed the infection in question, there is no physical evidence that the donor was, at the time of donation, infected.

There is only an implication that the donor may have been infectious. To start a process of searching for an individual, outside of a confidential approach based on the information in the donor record, opens up the risk that others may find out that the individual is being investigated for HIV, when in fact they did not have the disease.

I note that I wrote that we had some information that the donor had relocated to another part of the country and we contacted the Donor Services department of the Transfusion Centre covering that area, and they had no record of the individual. See DHSC0020840_041.

I appreciate that this is a balance between two risks. If there was definite evidence of infection, then that would be a different matter.

With the benefit of hindsight, I probably should have considered taking some further action to track down the donor. I do not have the information now, as to how likely it was that this donor was infected.

I note that I said that

> We searched our records and are happy that no one else could have been at risk.

178(a) Our obligation to donors with respect to infection is a balance that depends on likelihood of infection. If there is definite evidence, then all steps should be taken to contact the individual. If it is only a possibility of infection then the approach needs to be more careful and perhaps limited.

178(b) I do not have access to the Standard Operating Procedures used. However in general, if informed of a recipient of blood or blood products who has become infected, then the records of the donors whose blood/blood component was used would be examined. If each donor had donated again, the infectious disease test result would be checked. For any who had not donated again, contact would be initiated, with the limitations already described.

My report on the investigation of the case reported in the media is shown as an attachment to my letter to Dr. Rejman at the DoH and shows that the Centre did go to considerable lengths to follow up donors, donations and recipients in this case. See DHSC0020840_041, pages 2 to 6.

179. Ethical Obligation To Inform

The question 'Did you consider there was an ethical obligation to inform patients who may have received transfusions from infected donations' is perhaps not the right question. How do you inform patients who 'may' have received a transfusion. They either did or they did not.

If transfusion records showed that someone received blood from an individual who subsequently tested positive for an infection, (but at the time of the donation, that test had not been in use), then yes, they should be informed and tested.

As described in the case referred to in DHSC0020840_041, some recipients of blood from potentially infected donors, based not on a later positive test, but on the fact that their donation or part of it went to a recipient who subsequently became infected, were contacted and tested (in that case for HIV).

180. Local Look Back

I am not sure what this question is meant to elicit.

Section 16: My relationship with commercial organisations

181. Have you ever

181(a) provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or importation and/or sale of blood products

No.

181(b) received any pecuniary gain in return for performing an advisory/consultancy role for a pharmaceutical company involved in the manufacture, sale and/or importation of blood products

No.

181(c) sat on any advisory panel, board, committee or similar body, of any pharmaceutical company involved in the manufacture, importation or sale of blood products

No.

181(d) received any financial incentives from pharmaceutical companies to use certain blood products

No.

181(e) received any non-financial incentives from pharmaceutical companies to use certain blood products

No.

181(f) received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company

No.

182. Declaratory Procedures

I was not aware of any such procedures being in place.

183. Medical Research

Have you ever undertaken medical research for or on behalf of a pharmaceutical company involved in the manufacture, importation or sale of blood products

No.

184. Research Results

Have you ever provided a pharmaceutical company with results from research studies that you have undertaken

No.

In July 1991 the Centre did provide the HCV test manufacturer, Abbott, with data on the initial and repeat reactive rates for its test. The information was, I believe, used for a poster at the 3rd International Symposium on HCV. I did not receive any remuneration for providing this data. See 'Abbott RR Data Poster', (WITN6935029).

185. Declaration of Funding

Not applicable.

Section 17: Relationship between blood services

186. Engagement with SNBTS and NIBTS

I did not 'often' engage with the SNBTS, but I did meet and discuss issues with some of the Directors. I did have engagement with the then SNBTS Chief Executive.

In 1994 I did undertake a hospital satisfaction survey for the Glasgow Transfusion Centre, at the request of the Director, Dr. Ruthven Mitchell.

Although I met the Director of NIBTS, we had very little 'engagement'.

186(a) There was no formal arrangement in place for cooperation with SNBTS or NIBTS.

186(b) At a scientific/laboratory level, there was more contact and I was happy for this to occur. There were no restrictions in place on making contact or discussing issues for these staff or for heads of other departments.

187. UK-wide policy

I am not sure what this question is trying to elicit. There was a National Directorate for England and Wales and I assume that issues of policy were discussed with SNBTS.

I note that Dr. Gunson stated at the last Directors meeting (NHBT0018188):

> Dr. Gunson confirmed that contact with the SNBTS would be maintained by regular Meetings between himself and Professor Cash.

188. Morbidities and Fatalities

I do not recall seeing any such comparative statistics.

Section 18: Reform of the NBTS

189. National Directorate

As seen in some of my correspondence with the National Directorate, I was not impressed by its performance.

Discontinuing national meetings of Centre Directors and separating Centres from national discussions, such as discussions with advisory bodies and the DoH, left the Newcastle Centre in the dark on issues, perhaps receiving limited reports at regional meetings.

My comments in section 2 and 3.1 of NHBT0001864 lay out several of the areas where I thought that a 'National Directorate' could have provided considerable benefit to the NBTS and its individual centres.

190. Consistency

I have already commented on consistency. Consistency of outcome and adherence to Statutory requirements were required. How that was achieved was of much less importance.

As I said in NHBT0001864 the National Directorate should have considered setting minimum acceptable standards, allowing individual Centres to exceed these. Trying to set absolute standards tends to result in

a Idiosyncratic standards pushed by the loudest voice in the group

b Lowest common denominator standards

191. Remit and composition of the NBA Executive

This is not a topic that I am qualified to opine on.

192. Pre-NBA meetings

As I wasn't responsible for setting up the meeting structure, I cannot comment on their intended purpose.

The pre-meeting as outlined in the question of course differed from the Executive meeting. One was executive, the other was not.

193. Revised Proposal

An alternative proposal was put forward by a group of Centre Directors/Chief Executives.

193(a) As the NBA went ahead in the form it did, I can only assume that the DoH did not take on board our proposals. Indeed I didn't see anything in our proposal that made it through into the NBA.

193(b) The NBA did not appear to meet some of the objectives, although I don't have a copy of the final alternative proposal. How the NBA has performed vis-à-vis the alternative proposal in the years since I left the service, is not something I can comment on.

194. NBA Leadership

Please explain your views on the need for centralised responsibility for RTCs and the importance of consistency in policy decisions.

Once the Regional Transfusion Centres were transferred to the NBA, as noted in the question,

> '... RTCs would be required to follow leadership provided by the NBA Chief Executive and conform to decisions'

it was inevitable that policy would be directed centrally by the NBA.

195. Leaving the NBA

As Director and then Chief Executive at the Newcastle Transfusion Centre, the Northern RHA gave me considerable latitude to develop the Centre. When I started it was something of a backwater and at times almost

Dickensian in its operations (large ledgers being completed by clerks sitting on high wooden stools), and almost total lack of computerization.

I was very fortunate in finding that the Centre had an enormous pool of talent, with skilled, dedicated individuals who wanted to make improvements. I was in a position to harness that talent, to listen to their proposals and re-engineer the Centre.

Having had the opportunity to do this and to have been able to see individuals give so much to the service, I was reluctant to find myself in a position of following orders from a centralized organization, which I was likely to be unable to influence.

In addition to this, when I was offered the position of Director, I had set myself something of a limit. I felt that after five years or so I should move on, not wanting to stagnate in the job. By the time the NBA was set up, I had been in post for about six years, so the time was right for a move.

Although I did apply for one of the new NBA zone manager positions where I might have had a little more autonomy, the introduction of the NBA was the prime motivating factor in my decision to leave my position as Chief Executive of the Northern Region Blood Transfusion Service.

Section 19: Other matters

196. Publications

None

197. Other Issues

None

Statement of Truth

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

Signed GRO-C

Dated: 8th January 2022

Table of Exhibits:

Date	Notes/ Description	Exhibit number
Undated	Transfusion - Do We Have Any Choice. Notes for a talk prepared by HL, used in: Qn. 4	WITN6935018
December 1992	Computerization Summary 1993/94. December 1992 draft of the 1993/94 Clinical, Service And Business Plan	WITN6935019
Undated	Percentage of Red Cells Issued as Whole Blood 1985/86 to 1993/94	WITN6935002
Undated	Plasma Dispatched to BPL 1985/86 to 1993/94	WITN6935003
Undated	Plasma Produced 1991/92 to 1993/94	WITN6935004

Undated	Donors Bled Per Year 1985/86 to 1993/94	WITN6935005
Undated	Donors Bled 1947 to 1994	WITN6935006
Undated	Attending & Bled 1985/86 to 1993/94	WITN6935007
Undated	Donors & Place of Work Post 1979	WITN6935008
Undated	Industrial Donations as Percentage of All Donors Bled & Unemployment Rate	WITN6935009
Undated	Donor Information Leaflet 1989_90	WITN6935020
Undated	Donations 1985/86 to 1993/94	WITN6935010
Undated	Red Cell Exports 1991/92 to 1993/94	WITN6935017
May 1993	Plasma Procurement in England & Wales - 1992/93	WITN6935011
Undated	Plasmapheresis Donations 1985/86 to 1993/94	WITN6935012
Undated	Fresh Frozen Plasma to BPL 1981-1985	WITN6935013
Undated	No. of Units of Cryoprecipitate Produced 1982 to 1985	WITN6935014
Undated	Cryoprecipitate Issued 1985/86 to 1993/94	WITN6935015
Undated	Supply Contract Audit - Extract from draft contract document, referring to Audit and Good Manufacturing Practice	WITN6935034
Undated	Theoretical Plasma Procurement at a Minimum of 9 tonnes/million	WITN6935016
15 June 1992	Health Questionnaire 1992 Draft. Draft text for a document to be used during donor screening	WITN6935021

3 January 1991	Draft of letter to potentially infected donors, used for HCV trial	WITN6935035
14 April 1985	AIDS Notes 1985 - extract	WITN6935027
6 July 1989	The chiron corp test for NANB Hepatitis - Sheffield 1989 HCV Notes	WITN6935032
Undated	HIV Window Risk - Draft Overheads for a talk about HIV infection rates and window period risk	WITN6935028
17 July 1992	Donor Information Leaflet 1992 Draft. Draft for new donor call-up leaflet from July 1992	WITN6935022
Undated	Donors on Medication. Extract showing introduction and rationale for the Donors on Medication booklet used to screen donors	WITN6935023
18 May 1993	Hepatitis B core antibody memorandum from Dr Lloyd	WITN6935033
9 May 1991	Letter from Dr Lane to Dr Lloyd re introduction of HCV testing	WITN6935031
19 August 1991	Comments on Manchester PHLS Study	WITN6935030
13 March 1993	Autologous Transfusion Contract 1993/94. Draft for a contract for Autologous transfusion services in the Northern Region	WITN6935024
26 November 1993	Northern region blood transfusion service 'Quality Systems Policy'	WITN6935025
1 December 1993	Northern region blood transfusion service 'Quality Systems Policy' list of referenced documents	WITN6935026

3 July 1993	Abbott RR Data Poster	WITN6935029