Witness Name: Dr. Huw Lloyd

Statement No.: WITN6935037

Exhibits: WITN6935038

Dated: 2 February 2022

INFECTED BLOOD INQUIRY

SECOND 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: -

1. Addendum to answer to question 9.

A review and consequent reorganisation of the Newcastle RTC in 1992 resulted in the creation of a new Chief Executive position, responsible for "policy matters, quality and finance." You took up this position from October 1992. An Operations Manager position was also created to cover "all the operational aspects of the Centre from Donor Services, through Collection to Laboratory Services and Despatch" (NHBT0116389_057). To the extent not already covered by question 8, please explain how your role, functions and responsibilities changed when you became Chief Executive, and how the operation of the Newcastle RTC changed with the introduction of these new positions.

In this answer, inter-alia, I discussed the Centre becoming accredited to BS5750. This was a decision we made to improve the quality of the operation of the Centre using an acknowledged standard which was confirmed to having been met and continuing to be met by means of external audit (not from within the NBTS).

In NHBT0000027_030 'Guidelines for the Blood Transfusion Services in the United Kingdom 1989' it is of note that this statement occurs:

> 2.13
> In this chapter the Guidelines or principles for the establishment of a quality system will be presented. They are derived from the British Standard 5750
> (Quality Systems; specification for design, manufacture and installation).

2. Addendum to answer to question 16.

Please explain the system for blood collection at the Newcastle RTC during your employment there and how it changed over time.

In addition to the arrangements already described, there was a satellite office in Middlesbrough, known as the 'Teesside Office', managed by the Cleveland Area Donor Organiser, who reported to the Donor Services Manager in Newcastle. This office was responsible for the Teesside Area Voluntary Nursing Team, a unique voluntary team. Instead of Donor Attendants, volunteers, already members of the St. John Ambulance Brigade or the British Red Cross, cared for the donors and managed the blood collection. As with other donor sessions there was support from other volunteers, often from the WRVS, who helped with the refreshments and general donor assistance.

The Teesside Office provided the clerical support for the sessions, as well as managing the donors in the Teesside area and adjacent parts of Durham and North Yorkshire.

The Teesside Area Voluntary Team had been in existence since the first blood collection session in the area, held on 2nd September 1941, (WITN6935037), and in the 1980's and early 90's collected around 25,000 donations annually.

The team was trained and required to follow the same procedures and meet the same standards as the other, paid teams operating out of the Newcastle Centre.

When I started, two vehicles, a staff transport bus and an equipment lorry, were despatched daily from Newcastle to service the daily Teesside session. Later a driver was recruited locally to drive the staff bus, which was then housed locally. Other changes to session organization were promulgated to the Teesside team, such as the cessation of using a member of the laboratory staff for the haemoglobin testing.

In relation to the area covered by the Newcastle Centre I said the following

> 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.

I now think that we did hold a donor session in this area, but I don't think that we supplied any hospital across the border.

3. Addendum to answer to question 24 a.

The Inquiry understands that the Newcastle RTC procured plasma from blood donor sessions to produce fresh frozen plasma ("FFP") to provide to BPL (TYWE0000064; NHBT0101332_045). Please explain:

a. where the production of FFP took place;

In reference to the 'old' Centre in the Pathology Institute at the Newcastle General Hospital, this had been opened in 1956.

4. Addendum to answer to question 26.

As far as you are aware, how was plasma procurement at the Newcastle RTC funded throughout the 1980s?

Although I said I was not aware of the funding arrangements in the early 1980's, I see from recently provided documents in a report for the CBLA written by Dr. Gunson in January 1984 (CBLA0001800) that my predecessor as Director, Dr. A.K. Collins had responded to a request for information, summarized by Dr. Gunson as follows:

> For 1984-5
> Cannot obtain finance for SAG(M).
> For 1985-
> Has been unable to initiate discussions on plasma supply with R.H.A.

Further to Dr. Collins comment in 1983 or early 1984 above, regarding the lack of finance for blood processing utilizing the SAG(M) solution system, the minimal use of this at the Newcastle Centre is shown in Tables 11 & 13 of the study 'THE NATIONAL BLOOD TRANSFUSION SERVICE
IN ENGLAND AND WALES. AN ORGANISATIONAL STUDY' published in 1987, (CBLA0002392). The tables have data for 1985/86.

> From Table 11
> Newcastle (Region B in this table)
> NUMBER OF UNITS OF RED CELL PRODUCTS MADE IN 1985/86
> SAG(M) 2029.
> 74,773 units are shown as remaining unprocessed as whole blood.
>
> Only one other Centre is shown as less – Region 'J' shown as a blank for SAG(M) in table 11.
>
> From Table 13
> Newcastle (Region B in this table)
> Percentage of red cell products issued as SAG(M) 2%
>
> As before Region J had zero percent
> The next lowest (Region F) was at 7%
> Other regions ranged from 14% to 63%, with the overall for England and Wales being 31%

The issue of funding after I became director, i.e. the end of the 1980's is covered elsewhere in my initial statement.

5. Addendum to answer to question 27.

To what extent, if any, did the Newcastle RTC's perception of BPL's production capacity inform decisions about the quantity of plasma that would be supplied for fractionation?

To clarify the comment 'the poor state of the components production area' in the 'old' Centre, the rooms used for component production were in the basement of the Pathology Institute building, an area never intended for laboratory use.

6. Addendum to answer to question 29.

In your draft Litigation Statement, you wrote that the Newcastle RTC was "at the bottom of the league table for plasma production" for many years, and was not able to come close to its target for plasma procurement until the late 1980's (TYWE0000067). Please explain what you considered the barriers were to achieving sufficient plasma procurement at the Newcastle RTC. You may find NHBT0001580, DHSC0002247_077 and DHSC0002269_021 of assistance.

In support of my comment: 'Prior to 1985 – limited and outdated facilities', there is in a report for the CBLA written by Dr. Gunson in January 1984 (CBLA0001800) that my predecessor as Director, Dr. A.K. Collins had responded to a request for information, summarized by Dr. Gunson as follows:

> For 1985-
> Could not in any case increase supply in present premises.
> New R.T.C. should open in 1985/6.

7. Addendum to answer to question 46.

A Quality Audit of the Newcastle RTC's Blood Components Department in December 1989 noted that there were a number of areas in the production process for cryoprecipitate that could lead to a reduction in the quality of the cryoprecipitate (NHBT0073105_001).
Later, the Clinical, Service and Business Plan for Newcastle RTC for 1992-1993 stated that cryoprecipitate had improved as a result of a change in the production process (NHBT0074034_001, page 30).

In the initial part of my response regarding the quality of cryoprecipitate I said:

> 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.

Some further documentation regarding MCA inspections has been provided.

NHBT0203822 contains the list of issues from a 1992 MCA inspection. There are no 'major' or 'other' issues which refer to the production methods or processes for cryoprecipitate.

NHBT0203817_001 contains the list of issues from a 1993 MCA inspection. There are no 'major' or 'other' issues which refer to the production methods or processes for cryoprecipitate.

Thus it appears that the deficiencies reported in NHBT0073105_001 and summarized thus:

> There are a number of areas in this process which can lead to a reduction in the quality of these products.

were corrected.

The Centre developed a comprehensive quality control program, sampling specific numbers of products on a regular schedule. Examination of these records would identify how the cryoprecipitate tested, compared to existing standards. I do not have access to these records.

8. Addendum to answer to question 63 a.

You also wrote that the Newcastle HC could "probably have used more cryoprecipitate" but instead chose to use more commercial Factor VIII (TYWE0000064). Please explain:

a. what consideration the Newcastle RTC gave to increasing the production and use of cryoprecipitate in response to the growing awareness of the risks associated with Factor VIII concentrate in the 1980's;

It may be worth noting that in a letter published in the BMJ in June 1985, (PRSE0001917), the UK Haemophilia Centre Directors and others stated amongst other things:

> … we no longer consider that the use of cryoprecipitate or other non-heat treated concentrates is justified.

I do not recall reading this letter, but it does help to clarify issues around the perceived relative safety of cryoprecipitate compared to other available treatments in the minds of a major group of physicians and hence may have influenced the demand or lack of demand for the product.

WITN6935014 and WITN6935014 show that the demand for cryoprecipitate for most of the 1980's was fairly static in the region supplied by the Newcastle Centre.

9. Addendum to answer to question 147, point c.

Despite Dr Gunson's instruction to defer routine testing, the Newcastle RTC commenced testing on 24 April 1991 using the second generation Abbott test (NHBT0046745). This decision was criticised by Dr Gunson, your colleagues at RTCs, the ACVSB and Department of Health. The main criticisms advanced are set out below:

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

In addition to my previous comments, as a result of further documents provided, I note that the letter from Dr. Cash at the SNBTS is somewhat surprising given that he was a signatory to the letter to The Lancet shown in PRSE0001444 dated July 1987,' TESTING BLOOD DONORS FOR NON-A, NON-B HEPATITIS: IRRATIONAL, PERHAPS, BUT INESCAPABLE', in which he and his colleagues in the SNBTS argue for the introduction of NANB testing *now*, rather than *later,* (my emphasis), including commenting on the then upcoming 1988 European legislation on strict product liability:

> Looking at these three factors—producer's liability, competition, and value for money —we suggest that the decision which has to be made is when rather than whether the UK transfusion services follow the lead of the United States and other European countries in donor screening.

So on one hand he argues for testing as soon as possible, but then for HCV testing argues that a delay is acceptable, and severely criticises Newcastle for starting testing when it did.

I had not seen the article at the time in question.

10. Addendum to answer to question 154 a.

In a memo dated 18 June 1991, you wrote that your only regret in relation to the introduction of anti-HCV testing at the Newcastle RTC was that it was not introduced sooner (NHBT0000192_092). In your view, what was the earliest date on which anti-HCV testing could have been introduced:
a. by the Newcastle RTC;

In NHBT0000062_027, a letter from Dr. Gunson dated 5th February 1991, to all RTD's there is this:

> ANTI-HCV TESTING
> Further to my memorandum dated 22nd January 1991 I have had a meeting at the Department of Health concerning the financial arrangements for performing this test.
>
> It is proposed that the costs for the implementation testing will have to be charged on products issued from RTCs and be borne by the users. This will likely apply to the supplementary in addition to the screening tests.
>
> The Department intends to issue an Executive Letter on this subject to RGMs.

Given the typical cycle for developing budgets, the proposed information from the DoH about funding HCV testing which could have been issued no earlier than February 1991, is too late to allow for planning for the 1991/92 fiscal year.

It was fortunate that we had started the planning with the RHA back in 1989. If the first approach to the RHA had followed this information, it is easy to see how implementation of HCV testing would have been difficult and likely delayed further, let alone implemented earlier.

11. Addendum to answer to question 175.

Were you involved in setting up any HCV look back programmes during your time at the Newcastle RTC? If so, please describe this process and your role in it.

I also note that HCV look back was not officially implemented until the month I left the NHS.

In the DoH's 'Dear Doctor' letter of April 1995 (NHBT0002796_002), from the CMO about HCV look back, reference is made to an initial announcement in January 1995:

> I am sending this letter to inform you of the guidance and procedures for the look back exercise announced by Tom Sackville, Parliamentary Secretary for Health, on 11 January 1995, to trace, counsel and, if necessary, treat those people who may have been inadvertently infected with hepatitis C through blood transfusions.

Due to the timing of this announcement as I left the service, I am unable to provide any information on the action taken by the Newcastle Centre, which by that time was operating as a part of the new NBA.

Statement of Truth

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

Signed... GRO-C .....

Dated.... 2nd February 2022

Table of Exhibits:

Date	Notes/ Description	Exhibit number
01/09/1989	Guidelines for the Blood Transfusion Services in the United Kingdom 1989	NHBT0000027_030
01/01/1984	"Plasma Supply for Self-Sufficiency" Report to the CBLA by Dr. H. Gunson	CBLA0001800
01/10/1987	Report on "The National Blood Transfusion Service in England & Wales: An Organisational Study" by NHS Management Consultancy Services.	CBLA0002392
04/02/1992	Memorandum of Comments re: MCA Inspection report of the Northern Regional Transfusion Centre for 1992	NHBT0203822
22/01/1993	Letter from Dr Kavanagh to Dr Lloyd re: 8 Jan 1993 inspection, enclosing appendix of post-inspection discussion	NHBT0203817_001
22/06/1985	Letter from Bloom A L, Forbes C D & Rizza C R titled "HTLV-III Haemophilia and Blood Transfusion" published in the British Medical Journal, 22 June 198, 290.	PRSE0001917
04/07/1987	Testing Blood Donors for Non-A, Non-B Hepatitis - Irrational perhaps but inescapable, The Lancet	PRSE0001444
05/02/1991	Letter from H. H. Gunson to all RTDs regarding anti-HCV testing, financial arrangements, costs for the implementation of testing	NHBT0000062_027
03/04/1995	Letter from the Chief Medical Officer Dr K Calman to doctors regarding hepatitis C and blood transfusion lookback.	NHBT0002796_002

1991	Extract of book entitled ‘Teesside Area Voluntary Nursing Team for Blood Transfusion 1941-1991’	WITN6935038