Witness Name: Dr. Huw Lloyd

Statement No.: WITN6935039

Exhibits: WITN6935040-048

Dated: 18 March 2022

INFECTED BLOOD INQUIRY

THIRD 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. Donors testing positive for hepatitis C in the period April to September 1991

1.1. The first question from Ms Richards in the final session of my oral evidence on 09 February 2022, was about the number of donors testing positive for Hepatitis C after testing started in Newcastle until the 'common' start date of 01 September 1991.

This is taken from the official transcript (INQY1000183 page 48 09 February 2022, page 189 line 14 of the transcript):

MS RICHARDS: Dr Lloyd, there are a relatively small number of further questions.

The first is this: do you know how many donors tested positive for hepatitis C in the period April to September 1991?

A. No, unfortunately I don't. I did ask the Inquiry if data on positive results could be obtained. So unfortunately, no, I don't know.

1.2. As noted, I did not have that information. Subsequently I remembered that I had a handwritten document prepared in 1992 by our testing staff, shown as exhibit WITN6935040 which could be used to estimate the number of donors who tested positive in this period.

The document was probably prepared in April 1992 although it is not dated.

It shows:

(a) The HCV repeat reactive rate for each month from April 1991 to March 1992, and

(b) The HCV RIBA II confirmatory test results (as percentages) from 344 repeat reactive samples from April 1991 to the end of March 1992.

1.3. I created a spreadsheet shown as exhibit WITN6935041, using the number of blood and plasma donors bled for the months April 1991 to August 1991 (inclusive). This data comes from the spreadsheet previously identified to the Inquiry. The data for April 1991 is further adjusted for the date when testing started (24 April 1991), which is for blood collected on 23 April 1991.

The monthly HCV repeat reactive rates and the RIBA II confirmatory rates have been added to the spreadsheet to enable an estimate of the number of donations found to be repeat reactive to be calculated.

The document WITN6935040 also contains the percentage of repeat reactive samples found to be negative, indeterminate or positive by RIBA II testing. This data comes from a longer period of testing (April 1991 to March 1992) and as such is not fully representative of the RIBA II results from 24 April to 31 August 1991. The difference is unlikely to be significant in the context of what is already an estimate.

A further adjustment in the spreadsheet takes account of the fact that some of the donations tested came from plasmapheresis donors and their plasma would not have been transfused directly into patients.

1.4. The conclusion, as shown in the spreadsheet, indicates that there would have been about 17 donations with a RIBA II confirmed status during this period (excluding plasmapheresis donations).

1.5. In summary, during the period 24 April 1991 to 30 August 1991, there were just under 50,000 donations and an estimated 154 repeat reactive donations with around 17 RIBA II confirmed in donations that could have been used for direct transfusion to patients.

It should be noted that 'RIBA II confirmed' is not an absolute indicator of infectivity and a small number of RIBA II indeterminate donations may also have been infectious. As discussed below, some donations would have been made into more than one product. Some donations, although issued may not have been transfused.

The validity of the above calculations should be confirmed by someone more up to date with testing, as it is 30 years since I dealt with this material.

1.6. Although not pertinent to these calculations, the note on the data for 1992 [WITN6935040]: 'Previous RR's removed from this fig.' refers to the fact that repeat reactive (RR) results from donors repeat reactive on a previous donation and donating again were not included in the 1992 figures. The 1992 figures are now for a population which has had many repeat reactive/confirmed positive donors removed from the active donor panel and numbers for donors testing repeat reactive on a previous donation (but not confirmed positive) have been removed from the data. The fact that donors whose donations were found to be repeat reactive but not confirmed by RIBA II were allowed to donate again followed the HCV testing algorithm. Donations found to be repeat reactive were not used for transfusion.

1.7. In addition to the RIBA II confirmed positive donations, there are considerations as to how many products for local transfusion use, i.e. into patients, as opposed to being sent for fractionation, were on average, made from each donation.

I can provide an estimate based on information for the fiscal year 1991/92 held on a spreadsheet still in my possession as previously indicated to the Inquiry.

Exhibit WITN6935042 shows data from the original spreadsheet together with new calculations which show that approximately 1.2 locally transfusable items were issued from each tested donation in 1991/92.

1.8. I hope that this goes some way to answering the question.

2. Date by which all units for transfusion, would be negative for the HCV antibody

2.1. There was some lack of clarity in my answer to the question posed by Ms. Richards as shown in the official transcript, INQY1000183 page 32 09 February 2022, page 128 line 1 of the transcript
[some repetition due to audio issues removed]:

> Just in terms of the mechanics of it, first of all, Dr Lloyd, is this right -- is it right to understand that ... routine testing of donations began on 24 April but there'd also be a period of needing to test what was held in stock and so on, and is that what feeds, then, into this last sentence, all units will have been tested from 1 July?
>
> How do we understand the reference to 1 July?

2.2. I have re-read the letter referred to in the question put by Ms Richards, [NHBT0000074_010]. During my oral testimony, due to the passage of time and limited information, my recollection was that we probably did not actually meet the 1st July 1991 date for all blood and blood components for transfusion, to be Hepatitis C antibody negative.

I have had an opportunity to review the relevant documents as well as some other documents still in my possession. The result of this is that I am now sure that the 1st July date I referenced in several contemporaneous documents as the date by which all blood and blood components for transfusion in the region supplied by the Newcastle Centre would be HCV antibody negative, was correct.

2.3. In 1999 Dr. Barbara and Dr. Gunson [NHBT0088813_002 page 2] disputed this:

> ... However, we can only conclude that he intended to begin testing in April 1991, since he used the specious argument for taking this premature action that he wished to ensure that all

products for issue had been tested by 1 July (letter from H.Lloyd to H.H.Gunson, 1/5/91,U 37).

The reasons why we regard this argument untenable is that the two commonest blood products, platelets and red cells, have expiry dates of five and 35 days respectively. It would not have been necessary to begin routine screening during April to ensure that these products were tested prior to issue on 1 July 1991. The third product commonly issued is fresh frozen plasma which has a shelf life of one year. Special arrangements would have had to be made for this product since testing in April would not have been effective to ensure that all of this product, including stocks held at hospitals, was tested by 1 July.

2.4. Regarding the date by which the Newcastle Centre would have all blood and blood components negative for HCV antibody.
As follows, there are contemporaneous documents that show I had intended to meet the 1st July date, then reported the Center's progress on meeting that date and finally had remaining untested units withdrawn from hospital blood banks to complete the 1st July 1991 implementation.

(a) In a letter to Mr. Vickerman, Executive Director, Human Resources, Northern Regional Health Authority dated 30 April 1991 [NHBT0000191_162]:

> I therefore decided to continue with our original plans to start testing in April so that all units for Transfusion were negative by 1st July 1991.

(b) My letter to Dr. H H Gunson, dated 1st May 1991 [NHBT0000074_010]:

When a common date of 1st July was circulated some time ago, I made a decision to start testing in April 1991 so that we could be assured that not only were all issues of blood and blood components negative for the antibody but that all units transfused from that date were negative.

(c) A letter from Dr.Gunson to all RTDs dated 5th May 1991 [NHBT0000192_024]:

As you may know Dr. Lloyd decided to implement routine anti-HCV testing approximately two weeks ago in order that all products issued from the Northern RTC by 1st July 1991 will have been tested. He is using 2nd generation Abbott ELISA.

(d) A letter from me to Dr. Bassendine, Senior Lecturer/Consultant Physician, at the Newcastle Freeman Hospital, dated 29th May 1991 [NHBT0000192_069]:

The Northern Region Blood Transfusion Service started testing all blood donors for Hepatitis C antibodies at the end of April 1991. The aim at that stage was to ensure that all blood and blood components available for transfusion would be negative for Hepatitis C antibodies by 1st July 1991.

(e) I said in my witness statement [WITN6935001] in answer 156(b):

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.

From a document in my possession, an internal memo to me regarding the introduction of HCV testing, dated 15 March 1991, [WITN6935048] which covers several preparedness issues, one of the issues relates to the stock of frozen products for local use:

> Mrs Ashford informs me that at the present we are holding relatively low stocks of frozen products and therefore we should have a relatively short period of five to six weeks where we are holding stocks with mixtures of HCV and non-HCV tested components.

Note: 6 weeks from 15 March 1991 is 26 April 1991, and assuming that there was no significant change in the amount of product in stock, 6 weeks from 24 April 1991 would have been 05 June 1991.

(f) On 21st May 1991, as a post script to a further letter to Mr. Vickerman at the RHA, another document in my possession [WITN6935044], I included this:

> p.s. We are ahead of schedule on Hepatitis C testing. We will have no difficulty in meeting the 1 July, 1991 target and may meet the target by mid June.

(g) As confirmation that we did meet the target, it can be seen from the table WITN6935045 (taken from a database in my possession, as previously notified to the Inquiry), that a large number of frozen products were returned to the Centre in July of 1991. This would be due to a withdrawal of any remaining untested product in June.

In that month, blood banks in the Region returned 217 units of FFP, 316 units of cryoprecipitate and 30 units of cryo-supernatant.

These figures compare to 3-monthly average returns for April, May & June of 64, 27 & 1 units respectively and for the eight remaining months of the year, average monthly returns were 32 units of FFP, and 14 units of Cryo. and just one unit of cryosupernatant in those eight months.

2.5. Conclusion

As a result I am highly confident that the Newcastle Centre did meet the 1st July 1991 target to have all blood and blood components issued from hospital blood banks in the region, negative for HCV antibody.

3. Re: question 147 put to me by the Inquiry

I was asked at the end of this question:

> 'With reference to these documents, please set out your views at the time on the criticisms raised. Have your views changed since?

One of the documents I was referred to in this question was NHBT0088813_002, dated 17 March 1999 entitled:

> UNILATERAL INTRODUCTION OF ANTI-HCV TESTING AT NEWCASTLE RTC IN APRIL 1991
> A joint statement by J.A.J.Barbara and H.H.Gunson

which started:

> We consider that the premature action taken by Newcastle RTC with respect to anti-HCV screening of blood donations was an unsound policy for the following reasons ...

At the time I prepared my written answers I was not able to refute some of the statements in the document, but on subsequent consideration and finding some additional documents, I am in a position to make a further statement, which I believe more accurately reflects the position of the Newcastle Centre in 1991.

Three issues I wish to re-consider are:

(a) Date by which all units for transfusion, would be negative for the HCV antibody,

(b) Superiority of 2nd generation test over 1st generation test, and

(c) Preparedness for confirmatory testing.

3.1. Date by which all units for transfusion, would be negative for the HCV antibody.

This has been addressed in item 2, above and clearly shows that the Newcastle Centre did meet the 1st July 1991 date for having all units negative, and that the April start date was a sound decision for ensuring that the 1st July date was met, the arguments being neither specious nor untenable as stated by Dr. Barbara and Dr. Gunson in the 1999 document.

3.2. Superiority of 2nd generation test over 1st generation test.

The Joint Statement under a heading 'Inadequate infrastructure for routine screening', includes this:

> 2.1 Superiority of second compared with first generation tests
> Newcastle RTC commenced screening using Abbott second generation tests. Since there was no proof, apart from information from the manufacturers, that second generation tests were preferable to first generation tests ...

However there was information from another source that the Abbott 2nd generation test was both satisfactory and indeed superior to the first generation test.

On 6th February 1991 I reported on a conversation with Dr. Gunson [WITN6935046]. In that memorandum I passed on Dr. Gunson's

comments on the testing of the Abbott 2nd generation test in the Glasgow Centre:

> Apparently Abbott's second generation test run in Glasgow on the 69 positives which were repeatably positive by the first generation test in the recent trial, found that 7 samples were positive. 6 of these were then found to have been the ones confirmed to be positive by the Reference Centres. Dr. Gunson also mentioned that only 6 samples were confirmed to be positive by the Reference Centres in the recent trial. All three Centres found the same 6 samples as being positive. Thus the rate of confirmed positives is 6 in 10,000. Of the repeatable positives in the trial', the rate is apparently approximately 1 in 10 confirmed.

Whilst this was not a substantive trial, it clearly showed that the 2nd generation test performed well. I also note that at this time in February 1991, Dr. Gunson was suggesting that the 2nd generation test could be introduced in June, well before the later plan for a further trial. I included this in the same memorandum:

> He [Dr. Gunson] seems to think that this date in the middle of June might make it possible for Abbott to be able to introduce their second generation test, which is currently embargoed due to contractual problems.

This does not seem to suggest that Dr. Gunson had a fundamental problem with introducing the 2nd generation test. It is not of course an unequivocal statement that the test is satisfactory.

I also note that Dr. Gunson was present at the Advisory Committee on The Virological Safety of Blood meeting held On 21 November 1990 [NHBT0000073_018].

Under the heading 'HEPATITIS C TESTING (ACVSB 8/1 & 8/7)', Minute 13 from that meeting includes this:

> 13. Several members of the Committee were able to confirm that better tests were about to be issued. ...

Given that this committee (the ACVSB) was, in Dr. Gunson's words 'a powerful committee' [NHBT0000025_001] and that he deferred issues of viral safety to it, it is not unreasonable to consider that Dr. Gunson would already have accepted that the 2nd Generation tests were 'better' than the 1st generation tests.

To imply that Newcastle started testing with an unacceptable test was unwarranted and it should also be noted that we had in any case, been prepared to start testing with the first generation test.

3.3. Preparedness for confirmatory testing.

The Joint Statement includes this:

> 2.2 Confirmatory testing, counselling and medical referral of donors.
>
> Systems for confirmatory testing, counselling and procedures for medical referral of blood donors found positive for anti-HCV were not in place when Newcastle commenced screening.

(a) In an internal memorandum from the Centre's microbiology testing department to me dated 26 September 1991, as shown in WITN6935047, there is this in the first paragraph:

> 1 Confirmatory Results from Newcastle Public Health Laboratory (PHL)
>
> Abbott anti HCV screen repeat reactive samples have been sent to Newcastle PHL since the 23 4 91 for anti HCV

> confirmatory testing by Ortho Recombinant Immunoblot Assay (RIBA) 2nd generation. So far 165 results have been returned with a current turn around time of one week. However the results we receive are not recorded in accordance with the manufacturers' recommendation but by their own criteria which seems to depend on the strength of the Ortho screen result they obtain. See Fig 1.

This shows that the Centre included confirmatory testing from the start of HCV testing. The reference to '23 4 91' shows that the first donations tested on 24th April had been collected the day before, Tuesday, 23rd April 1991.

(b) In my letter to Dr. Bassendine, on 29th May 1991 [NHBT0000192_069] I included this:

> Those who are confirmed by RIBA2 and PCR will be assumed to be infectious and in due course we will be writing to the donors and their General Practitioners, suggesting that they be referred to yourself.

Although this was written about a month after testing started, it should be noted that the Centre had already participated in the first generation HCV study in late 1990 and, as appropriate, donors had been referred to their General Practitioner with an indication that they may then be referred to a specialist [WITN6935035].

As shown from (a) & (b) above, to imply that Newcastle started testing without confirmatory testing, or a plan for referral in place was inappropriate and incorrect.

4. The Joint Statement

Having been asked to comment on the criticisms levelled at myself and the Newcastle Centre in the 1999 Joint Statement from Dr. Barbara and Dr.

Gunson [NHBT0088813_002], I have looked at some associated documentation.

4.1. Dr. Gunson to Simon Perl [NHBT0088808]

It may be of note that Dr. Gunson wrote to Simon Perl of Davies Arnold Cooper, Solicitors [NHBT0088808], on 16th February 1999, (I believe this was in response to litigation with the NBA), and included this:

> 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.

This was dated 16th February 1999, a month before the Joint Statement was issued.

4.2. Dr. Gunson to Dr. Barbara [NHBT0088807]

On 22 February 1999 Dr. Gunson writes to Dr. Barbara [NHBT0088807] saying inter-alia:

> You are correct. Systems for the *confirmatory testing, counselling and medical referral* were not in place when Newcastle commenced testing, (my emphasis).

That phrase 'confirmatory testing, counselling and medical referral' is identical to a heading used in the Joint Statement:

> 2.2 Confirmatory testing, counselling and medical referral of donors

The 22 February 1999 letter to Dr. Barbara also has several references to the Newcastle Centre or to myself, and starts by referring to 'Newcastle's unilateral decision to introduce anti-HCV tests'. The letter appears to be almost entirely about Newcastle's actions and is in response to a document or documents from Dr. Barbara to Dr. Gunson, although I do not know if any of this correspondence has been obtained by the Inquiry.

4.3. Conclusion

Thus it may be assumed that the 'Joint Statement' issued in 1999 was what Dr. Gunson was proposing to Simon Perl of Davies Arnold Cooper 'to put forward', in order to 'demonstrate that the decision taken by Newcastle was maverick and premature'.

Statement of Truth

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

Signed..... GRO-C

Dated... 24th March 2022.

Table of Exhibits:

Date	Notes/ Description	Exhibit number
01/01/1992	Handwritten note: Percentage of Repeat Reactive Rate HCV	WITN6935040
22/02/2022	HCV Testing April to August 1991	WITN6935041
22/02/2022	Locally Transfused Blood and Components 1991/92	WITN6935042
08/01/2022	First written statement of Dr Huw Lloyd	WITN6935001
15/03/1991	Memorandum from Dr Doughty to Dr Lloyd	WITN6935048

21/05/1991	Letter from Dr Lloyd to Mr Vickerman re Hepatitis C testing	WITN6935044
22/02/2022	Frozen Product Returns	WITN6935045
06/02/1991	Memorandum from Dr Lloyd to Mr Masterman	WITN6935046
26/09/1991	Report on the current status of anti HCV testing	WITN6935047
09/02/2022	Transcript of Dr Lloyd's oral evidence to the IBI dated 9 February 2022	INQY1000183
03/01/1991	Letter from A K Collins re positive donor letter	WITN6935035