

TOPIC C5a

The information given to patients (or their parents) about the risk of non-A non-B Hepatitis and the severity of the condition before their treatment with blood or blood products.

- 1. The nature and extent of the information provided to patients (or their parents) about the risk of acquiring NANBH/Hepatitis C through blood and blood products.**

and
- 2. The nature and extent of the information provided to patients (or their parents) about the possible consequences of NANBH/Hepatitis C infection.**

and
- 3. The manner in which information was provided to patients (or their parents) about the risk of acquiring NANBH/Hepatitis C through blood and blood products and the possible consequences of NANBH/Hepatitis C infection.**

The information given to patients needs to be considered with reference to the developing knowledge of the virus during the relevant period. This is covered elsewhere in our submissions¹.

The Inquiry heard evidence about what patients should have been told during the reference period.² Dr Alexander made it clear that from 1985 onwards patients should have been informed that they had a disease, the prognosis for which was not as benign as previously thought and that as many as a fifth would go on to develop serious liver disease.

¹ Post Transfusion Hepatitis (PTH) was used to describe any hepatitis which appeared to have been caused by transfusion. Before 1974 parenterally transmitted hepatitis was generally thought to be hepatitis B or "serum" hepatitis. The Prince paper in 1974 (see PR para 6.28) recognised that there appeared to be cases of post transfusion hepatitis which could not be explained as hepatitis B. This led to the identification of another unknown form of post transfusion hepatitis, called NANB hepatitis, as a diagnosis of exclusion and was regarded as "benign". In his evidence, Professor Thomas identified papers published over the period from 1978 to 1982 (including a study of his own and the study by the Sheffield team including Eric Preston in 1978) which started to recognise that NANB Hepatitis was not as benign as has had been thought. Professor Thomas said that these studies painted a picture that the disease was not benign and which could, in some cases, be very serious. Professor Thomas indicated that the "turning point" came in 1985 with the publication of the updated Sheffield research (Hay & Ors).

² Transcript 17/01/12 (Day 85): 1410(129) to 142(3) (Dr Graeme Alexander)

In our submission patients being treated with blood and blood products in the 1970s and 1980s would not have appreciated that there was a risk of receiving a largely symptomless viral infection, whose long term effects were unknown but were not thought to be serious, unless they were told. In our submission the weight of the evidence indicates that generally patients were not told specifically about the risk of Non-A Non-B hepatitis associated with blood and blood products.

In relation to the question of the information that was provided to haemophilia patients (or their parents), what patients were told would have been dependent on the practice in the centre where they were treated. In this regard there is a great deal of evidence before the Inquiry from patients who maintain that they were never warned about the risk of contracting Non-A Non-B hepatitis or Hepatitis C through blood or blood products.³ Some had even been reassured that factor concentrates were safe.⁴ Furthermore, prior to their diagnosis with Hepatitis C, many of these patients had no idea that they were infected with Non-A Non-B hepatitis or even that their liver function was being monitored, and they assumed that their blood samples were being used to monitor their factor levels.⁵ Although specific diagnoses of Non-A Non-B hepatitis were frequently made in the late 1970s and early 1980s this information was not shared with the patients⁶.

Prior to 1985 some patients may have been told that there was a risk of “hepatitis” or hepatitis A or hepatitis B, but the risk of Non-A Non-B hepatitis was not made clear. By 1985 it was understood that Non-A Non-B hepatitis was not as benign as previously thought and that some patients would go on to develop serious liver disease. Studies of liver biopsies carried out from the late 1970s showed that clinically symptomless patients did in fact have liver damage. It

³ Preliminary Report, Chapter 4, 4.33 to 4.50; Transcript 08/12/11 (Day 75): 10(23) to 11(3) (STEPHEN); Transcript 10/01/12 (Day 81): 17(23) to 18(5) (ALEX); Transcript 09/06/11 (Day 30): 102(22) to 103(8) (DAVID); Statement of Core Participant: PI119JP at paragraph 11; Statement of Core Participant: PI055JP at paragraph 7 Transcript 13/12/11 (Day 77): 7(5) (COLIN); Transcript 08/12/11: 11(3) (STEPHEN); Transcript 09/06/11 (Day 30): 102(22) to 103(8) (DAVID); See also Chapter 4 of the Preliminary Report 4.33 – 4.50

⁴ Transcript 10/01/12 (Day 81) (17(24) to 18(5) (ALEX) - Alex’s father was told that all blood products were heated and safe; Transcript 07/06/11 (Day 28): 17(6) to 18(5) (CHRISTINE) – Christine and her husband had specifically asked about the risks and been told that there were risks with everything and the query had been dismissed

⁵ Transcript 10/01/12 (Day 81): 17(23) to 18(5); 25(21-23); 26(13-18) ; 32(19-25) (ALEX) – Alex’s parents were initially told that all blood products were safe and were subsequently told that he was being tested for Non-A Non-B, but did not know what this meant as it was never explained to them; Transcript 09/06/11 (Day 30): 102(22) to 103(8) (DAVID); Statement of ELAINE’s brother-in-law: [WIT.004.0136] at paragraph 11; Statement of Core Participant: PI119JP at paragraph 13; Statement of Core Participant: PI055JP at paragraph 12; Statement of Core Participant: PI119JP at paragraph 14; Statement of Core Participant: PI066MF at paragraph 9

⁶ Statement of Core Participant: PI119JP at paragraph 13; Witness statement NIOGO115 at paragraph 6; Preliminary Report, Chapter 4, paragraph 4.72

began to be appreciated that the disease was progressive, and it would have been appreciated that the condition of symptomless patient may well deteriorate significantly. We have been unable refer to any evidence from any patient which shows that that any of this developing knowledge was actually shared with that persons. In our submission, this developing knowledge ought to have been shared with the patients by those treating them. It was not.

It is clear from the evidence before the Inquiry that until April 1987 any patient receiving an SNBTS concentrate would almost certainly be infected with Non- A Non-B hepatitis as result. This fact was known by those administering the treatment but generally speaking was not shared with those receiving it at any point. The failure to share this information with patients is important in understanding the resentment on their part as to the extent to which they were kept in the dark about the consequences of the treatment that they received.

Evidence was provided to the Inquiry by three medical practitioners⁷ who treated haemophilia patients at the Glasgow Royal Infirmary, Yorkhill and Edinburgh Royal Infirmary respectively and who would have been responsible for giving the relevant information to patients (or their parents). Their witness statements⁸ make reference to a document⁹ purporting to be a collective response prepared on behalf of past and present haemophilia centre staff in Scotland on Topic C5 (“the Collective Response”). In our submission the “Collective Response” and the evidence of these witnesses is couched in such general terms that it is of little assistance to the Inquiry in terms of understanding what was actually said to individual patients or their parents about NonA NonB hepatitis or whether this was done in a way that patients (or their parents) would understand. We are unaware of any guidance available during the reference period written or otherwise about what patients should be told about the risk of Non A Non B hepatitis or hepatitis C available during the reference period.

In relation to patients who were infected through blood transfusions, the Inquiry has heard evidence from patients who confirmed that the risks of acquiring Non A Non B hepatitis from a transfusion were not discussed with them before operations.¹⁰ The Inquiry has not heard evidence from any medical practitioners about whether or not the risks would have been discussed, or whether there were any guidelines or protocols in place about what patients

⁷ Professor Lowe, Dr Gibson and Dr Ludlam. Dr Cachia from Ninewells Hospital did not address the issue of information given to patients about the risk of NANBH before treatment

⁸ [PEN.018.0839]; [PEN.018.0824]; [PEN.018.0832]

⁹ [PEN.018.0649]

¹⁰ Transcript 13/12/11 (Day 77): 100(7-21) (GORDON); Statement of ANNE: [WIT.005.1112] at paragraph 2; Transcript 07/06/11 (Day 28) 28(10 -23) (CHRISTINE); Statement of Core Participant: PI056SC at paragraph 3;

should be told. Often a transfusion will take place where there is no opportunity to discuss the risk beforehand. There is no evidence that the risks of developing Non A Non B hepatitis were discussed afterwards.

- 4. The absence of systems, guidelines and monitoring to ensure that all patients (or their parents) treated by the NHS in Scotland were given adequate and uniform information about the risk of acquiring NANBH/Hepatitis C through blood and blood products and the possible consequences of NANBH/Hepatitis C infection.**

There is no evidence of there being any system in place for ensuring that those treating patients with blood or blood products kept informed about developing knowledge about Non-A Non-B hepatitis during the reference period. There is also no evidence of any guidelines about what patients (or their parents) should have been told about the risks or consequences of infection.

- 5. The extent to which patients were aware of the risk of acquiring NANBH/Hepatitis C through blood and blood products and the possible consequences of NANBH/Hepatitis C infection, and whether communication of such information to patients was effective.**

This issue has already been addressed under 1 and 2 above.

- 6. The extent to which patients (or their parents) were afforded the opportunity to be involved in or to make informed decisions about their treatment with blood and blood products.**

In our submission it is clear that patients were not given sufficient information to make informed decisions about their treatment with blood or blood products throughout the reference period. The explanation for why this might have been the case is contained in the evidence of Vivienne

Nathanson¹¹:-.

“While some doctors and some practices worked in ways which would fit with current day expectations, this was far from always the case.

It is fair to say that the change from an essentially paternalistic, doctor-knows-best culture to one which the patient is at the centre of medical practice and his/her empowerment an essential element of the relationship between patient and doctor, has evolved at different rates in the practice of different doctors. The earlier the time frame under consideration the commoner an essentially paternalistic approach would have been.

Changes have occurred following clear expositions of good ethics, and supported by case law, education, and in particular training in communication skills to enable doctors to communicate with patients and their relatives in a sensitive and nuanced manner”

In our submission the experiences spoken to by the patients (in evidence and in statements) reflect the paternalistic attitude of the doctors treating them at the time. The risk of Non-A Non-B hepatitis was not discussed at all or certainly not in a manner that ensured that it was properly understood and patients were consequently not able to make informed choices about their treatment.

7. Lessons and implications that can be identified, and recommendations that can be made for the future, arising from the Inquiry’s consideration of topic C5a.

See joint recommendations for Topics B5 and C5

TOPIC C5b

The tracing and testing of patients who might have been exposed to the virus through their treatment with blood or blood products.

Information about testing and consent to testing

1. The nature and extent of the information given to patients about Hepatitis C and the

¹¹ See Transcripts days 37 and 84 23/06/11 and 13/1/12 PEN.012.0330 and PEN0180419

possible consequences of infection prior to testing.

and

2. The extent to which consent was sought and obtained from patients prior to testing.

and

3. The extent to which lessons learned from the HIV experience ought to have informed the approach to Hepatitis C testing.

The Inquiry heard evidence about the correct approach to testing for Hepatitis C between 1991 and 2000. In relation to whether or not patient consent was required, Professor Nathanson referred to a 1988 BMA publication “Philosophy and Practice of Medical Ethics”¹² which provided that “The basis of any discussion about consent is that a patient gives consent before any investigation and treatment proposed by the doctor. Doctors offer advice but the patient decides whether to accept it.” She explained that the best practice standard at the time¹³ was that doctors treat patients only on the basis of consent in that the patient makes the decision and the doctors offer advice and guidance. She also confirmed that best practice advice at the time was that testing was considered to be treatment.¹⁴ In relation to whether or a doctor should have told a patient that they were being tested for Hepatitis C, Professor Nathanson indicated that this would depend upon whether or not there had been prior discussion with the patient such that they knew that they had Non-A Non-B hepatitis and the test was merely a confirmatory test for the specific virus, but that it would still have been preferable to tell them.¹⁵

In relation to pre-test counselling, Professor Nathanson said that best practice at the time would have required doctors to give patients information about what was then known about the disease and to obtain their agreement to the test, but that prolonged pre-test counselling along the lines of counselling given prior to HIV testing was not required.¹⁶

In our submission, when Hepatitis C testing was introduced in 1991 doctors should have ensured that, prior to testing patients for Hepatitis C, the patients fully understood what they

¹² [PEN.018.0421] – Professor Nathanson indicated that this was the BMA guidance on medical ethics at the time.

¹³ based both upon this and upon the General Medical Council advice for the same year.

¹⁴ Transcript 12/01/12 (Day 84): 23(25) to 25(19) (Professor Nathanson)

¹⁵ Transcript 13/01/12 (Day 84): 56(3-23) (Professor Nathanson)

¹⁶ Transcript 13/01/12 (Day 84): 37(3) to 8(21) (Professor Nathanson)

were being tested for and why, and their consent obtained. However, the evidence before the Inquiry clearly indicates that this did not happen on many occasions.

There is evidence before the Inquiry from Professor Lowe, Dr Ludlam and Dr Gibson to the effect that when hepatitis C testing was carried out what was going on was explained to patients and their consent to it obtained. However, the Inquiry has evidence from patients, including patients who were treated at the Glasow Royal Infirmary, Yorkhill and Edinburgh, who did not know they were being tested for Hepatitis C.¹⁷ Furthermore, many of these patients were not aware that they had Non-A Non-B hepatitis.¹⁸ They did not know because they were had not been told what Non-A Non-B hepatitis was or what it entailed in terms of a risk to them. General warnings about “hepatitis” did not convey to patients the insidious nature of Non-A Non-B hepatitis or the adverse consequences it could have.

Prior to testing haemophilia patients for Hepatitis C those treating them should have ensured that patients knew that they had Non-A Non-B hepatitis and what the potential adverse consequences of that were. Patients should also have been informed that the test was likely to be positive. This would have ensured that patients were in a better position to come to terms with and understand the consequences of their diagnosis when it was eventually made.

Steps taken to trace individuals who might have been exposed

4. Why the look-back exercise was not initiated as soon as a screening test for anti-HCV became available.

The national look-back exercise to identify recipients of blood that might have been infected with Hepatitis C did not start until April 1995 although a test for Hepatitis C was introduced in September 1991

¹⁷ Preliminary Report, Chapter 4, paragraph 4.51 to 4.64; Statement of DAVID: [WIT.004.0007] at paragraph 12; Statement of ELAINE’S brother-in-law: [WIT.004.0136] at paragraph 11; Transcript 07/06/2-11 (Day 28): 17(6-11, 17(25) to 18(5)(CHRISTINE);

¹⁸ Transcript 10/01/12 (Day 81): 17(23) to 18(5); 25(21-23); 26(13-18) ; 32(19-25) (ALEX) – Alex’s parents were initially told that all blood products were safe and were subsequently told that he was being tested for Non-A Non-B, but did not know what this meant as it was never explained to them; Transcript 09/06/11 (Day 30): 102(22) to 103(8) (DAVID);Statement of ELAINE’S brother-in-law: [WIT.004.0136] at paragraph 11; Statement of Core Participant: PI119JP at paragraph 13; Statement of Core Participant: PI055JP at paragraph 12; Statement of Core Participant: PI119JP at paragraph 14; Statement of Core Participant: PI066MF at paragraph 9

Dr Alexander stated that the reason why look-back was not introduced in 1991 was that it was not known what to tell patients about the natural history of the disease at that time.¹⁹ His position was that since patients could not be told with any degree of confidence what was going to happen to them and given the lack of confidence in the tests and lack of available treatment look-back was not thought appropriate until 1995.²⁰

The Inquiry also heard evidence about why a look-back exercise was not implemented in Scotland in September 1991 but April 1985 when the national look-back was implemented. .

In June 1990 Dr Cash asked Dr Gillon to produce operational guidelines for blood transfusion service doctors in the context of counselling donors found to be anti-HCV positive. The final draft included a recommendation that a look-back be carried out. The justification for this was the desirability of informing recipients, the protection of others and so they could receive treatment with Interferon if the benefits of that form of therapy were confirmed.²¹ When the national look-back was ultimately introduced in 1995, much of what was contained in that document was used.²²

Dr Gillon's report was considered by the Medical Scientific Committee (MSC), who advised the SNBTS, at a meeting on 19 February 1991. It was decided that, "in light of national events", a look-back should not be introduced at that time.²³ Professor Cash could not recall what these national events were but suggested that he might have been informed that the Advisory Committee for Virological Safety of Blood (ACVSB), who advised the ministers, were against a systemic look-back and that he could have relayed this to the directors at the MSC meeting. However he said that by the end of 1991 his primary reason for not implementing the look-back was because he was concerned about the lack of treatment.

Dr Gillon told the Inquiry he felt strongly that look-back should have been implemented from September 1991 It was the ethical thing to do²⁴. As soon as anti-HCV testing became available in September 1991, he commenced a look-back exercise in the South East Scotland Blood Transfusion Service.²⁵ In November 1993 Dr Gillon, together with Dr Ayob, submitted a paper

¹⁹ Transcript 17/01/12 (Day 85): 123(3) to 124(18) (Dr Alexander)

²⁰ Transcript 17/01/12 (Day 85): 137(14) to 138(14) (Dr Alexander)

²¹ [SNB.005/5023]; [SNB.004.5074]; Transcript 18/01/12 (Day 86):8(17-22); 12(16) to 13(7) (Dr Gillon)

²² Transcript 18/01/12 (Day 86):17(10-13) (Dr Gillon)

²³ [SNB.009.5668]; Transcript 17/01/12 (Day 85): 32(12) to 33(3)(Professor Cash)

²⁴ Transcript 18/01/12 (Day 86): 31(7) to 32(15) (Dr Gillon)

²⁵ Transcript 18/01/12 (Day 86): 32(20-25); 38(17-19); 43(13-14) (Dr Gillon)

about this look-back exercise, which was accepted for publication in July 1994²⁶ which concluded that look-back was feasible with little in the way of extra resources and justified in terms of outcome.²⁷

Dr Cash told the Inquiry that after he attended a symposium on 8 October 1993 at which he learned about the latest treatment for Hepatitis C, he took the view that there was reason to start a look-back.²⁸ Thereafter further consideration was given was given to the possibility of implementing a look-back exercise in Scotland and by May 1994 a decision had been taken to implement the look-back on 1 June 1994. This was not done and look-back in Scotland was only commenced in April 1995 with the implementation of the UK national look-back.

The Inquiry has heard no evidence to suggest that the look-back could not have been implemented successfully in Scotland in September 1991. The short point is that Dr Gillon was right for the reasons he gave in 1991 and as explained to the Inquiry in his evidence. In our submission there was no justification for delaying implementation of a look-back exercise in Scotland until 1995 on the basis that there was no treatment available. Dr Hayes said that that Alpha interferon was introduced into clinical practice in about 1991/1992²⁹ and that the first opportunity that patients would have had to receive treatment would have been as part of a clinical trial.³⁰ By delaying the look-back exercise until 1995 patients were deprived of the opportunity of receiving treatment at the earliest opportunity. There were also other things that could have been done for patients even if no treatment was available. They could have been monitored and would have been available for treatment once it became available, and they could have been given advice about transmission and alcohol consumption. Testing could have been offered to their partners and children. Professor Nathanson also highlighted the ethical requirement that individuals have a right to know information about their health and bodies. It does not appear that any of these considerations were taken into account when it was decided not to implement the look-back exercise in 1991.

In our submission the delay in instituting the look-back exercise will necessarily have resulted in fewer recipients of Hepatitis C infected blood being traced and tested, both because of the measures introduced in 1991 to discourage previous drug users from donating blood and

²⁶ Transcript 18/01/12 (Day 86): 44(6-10); 48 (20-24) (Dr Gillon)

²⁷ Transcript 18/01/12 (Day 86): 72(7-14) (Dr Gillon)

²⁸ [PEN.018.0553]; Transcript 17/01/12 (Day 85): 68(9) to 72(11) (Professor Cash)

²⁹ Transcript 14/12/11 (Day 78): 51(21-25); 53(8) to 54(8) (Professor Hayes)

³⁰ Transcript 14/12/11 (Day 78): 54(9) to 55(6) (Professor Hayes)

because of the fact that, with the passage of time, the chances of being able to locate recipients is reduced.

5. The extent of the look-back exercise and its restriction to repeat donors.

and

6. The effectiveness of the look-back exercise in identifying patients infected with Hepatitis C through blood in Scotland.

The national look-back exercise that was implemented in 1995 was a targeted look-back which entailed the screening of donors to find those that were Hepatitis C positive, followed by a targeted look-back to their previous donations in an attempt to find the recipients.³¹

The approach that was adopted in the national look-back meant that in order to identify infected blood donors, the blood transfusion services had to rely on the donors coming back to make a donation. Dr Alexander pointed out that one of the problems with this approach was that around the same time people were being discouraged from coming back to give blood if they had a history of drug addiction. Furthermore, from 1985, because of HIV, the number of people coming back who had injected drugs in the past was falling each year. Dr Alexander said that for this reason the approach was flawed from the start.³² He suggested that an alternative approach might have been to go back through stored samples, but pointed out that in England this would have involved looking at 6 million samples over the previous three years, which would have involved three years of work by a service that was already under pressure, so it was decided that this was not practicable. He also pointed out that in Scotland there would have been many more samples as they would have gone back longer. He also said that this could only be done with an enormous amount of funding.³³

In his report Dr Alexander referred to a study by Soldan *et al* which estimated that only 5 per cent of the total number of HCV infections had been identified by the look-back exercise. Dr Alexander confirmed that this was a fair assessment and that the data of the look-back exercise

³¹ Transcript 18/01/12 (Day 86): 2(3-21) (Dr Gillon)

³² Transcript 17/01/12 (Day 85): 125(2-18) (Dr Alexander)

³³ Transcript 17/01/12 (Day 85): 125(19) to 126(2); 136(15) to 137(13) (Dr Alexander)

matched up with data on the likely frequency of Hepatitis C infection at that stage.³⁴ He explained that the reason for this small percentage was because the look-back exercise was based on donors coming back and being found to be positive, but that donors had stopped coming back because of the steps taken to discourage high risk donors from giving blood.³⁵

The Inquiry heard about further difficulties with the look back in terms of being able to match HCV infected donors with the correct recipients. In this regard Dr Alexander indicated that hospital records were needed to check that the blood had been transfused and they needed to know where the patient lived now, which could be 15 or 30 years later. He said that this was difficult not knowing who the GP was, not knowing the recipients current address and not even knowing if the hospital records were available, He said that even today hospital records continue to be destroyed not long after the patient has been there.³⁶

The shortcomings and limited efficacy of the type of look-back that was implemented nationally in April 1995 had been highlighted in a 1991 article³⁷ by Mike Busch. Dr Gillon indicated that this paper was probably important in the approach to look-back.³⁸

In our submission the limitations of the national look-back exercise should have been appreciated at the time that the look-back exercise was implemented and additional measures such as a public awareness campaigns should have implemented to ensure that as many recipients as possible would be traced and tested.

³⁴ Transcript 17/01/12 (Day 85): 136(1-8) (Dr Alexander)

³⁵ Transcript 17/01/12 (Day 85): 135(25) to 136(13) (Dr Alexander)

³⁶ Transcript 17/01/12 (Day 85): 126(9) to 128(3) (Dr Alexander)

³⁷ [PEN.019.2307]

³⁸ Transcript 18/01/12 (Day 86): 74(17) to 18(7) (Dr Gillon)

7. The number of patients infected with Hepatitis C through blood in Scotland who might not yet have been traced through the look-back exercise.

Given the shortcomings of the look-back exercise identified above there are people in Scotland who have been infected with Hepatitis C through blood or blood products who were not traced via the look-back exercise and who have not yet otherwise been tested for Hepatitis C. In this regard Professor Thomas indicated in his evidence that there is a group of individuals of unknown, but probably significant size, who may be infected with Hepatitis C but who are asymptomatic and destined never to develop complications.³⁹ Although this group includes people who may have experimented with drugs, there is no reason why it could not also include persons who were infected through blood and blood products.

In our submission, even if these people are destined never to develop complications they could still pose a potential risk of transmission. In this regard the Inquiry has heard evidence that Hepatitis C can be transmitted from mother to baby and sexually, although the rates of transmission are less than 5 per cent in each case.⁴⁰ The Inquiry has also heard evidence from a patient witness who was infected with hepatitis C through her husband.⁴¹

8. Whether adequate measures have been taken to identify patients infected with Hepatitis C through blood in Scotland who might not yet have been traced through the look-back exercise.

and

9. The number of patients and/or families of patients infected with Hepatitis C through blood in Scotland who have never been advised of their diagnosis and/or the source of infection.

Given the evident limitations of the look-back exercises as referred to above, it is submitted that additional measures, such as public awareness campaigns, should have been employed in

³⁹ Transcript 12/10/11 (Day 53): 6(2-15) (Professor Thomas)

⁴⁰ Transcript 11/10/11 (Day 52): 76(15-21) (Professor Thomas) but compare Transcript 17/01/12 (Day 85): 142(21) to 143(3) (Dr Alexander) where the rate of vertical transmission is given as 6% and the sexual transmission as hardly ever

⁴¹ LAURA

conjunction with the look-back exercise to ensure that as many recipients as possible were offered testing.

In his 1991 article Busche suggested that in light of the data showing very limited efficacy of previous look-back efforts, an appropriate response to the situation posed by HCV would be an aggressive education campaign for physicians and the lay public about the risks and benefits of transfusions. He suggested that there was a need to disseminate information about the risks of all transfusion-transmitted diseases, both to previous and future transfusion recipients, in a well-orchestrated and long-term education campaign. He also suggested that all physicians should be encouraged to keep detailed transfusion histories from their patients and, on the basis of clinical findings and dates of transfusion, to test their patients for relevant viruses or diseases. He was of the view that the long-term gain of a commitment would outweigh the short-term yield of any specific HCV look-back effort.⁴²

Dr Gillon told the Inquiry that the possibility of a public education campaign was something that had been considered by the MSBT and that to some extent this was done in the press conferences when the CMO's letter came out. He also indicated that the letter to doctors had included a statement that any patient with a history of transfusion who expressed any concern about Hepatitis C should receive a test.⁴³ Dr Alexander also gave evidence to the effect that at the time of the look-back there had been discussion about the possibility of having a television campaign inviting people who had received a transfusion at a certain time to come forward and be tested. He said that what had happened was that most of the people in his profession throughout the UK were invited on to local radio programmes two or three times over a year or two, and sometimes into television programmes, and they would invite people who had had a transfusion to come forward and be tested.⁴⁴ He said that alternative approach was to ask GPs to refer everyone from their practice who had been transfused, but that it turned out that GPs often do not know that a patient has been transfused and that neither do patients. In this regard information about transfusions are not routinely reported back to GPs.⁴⁵

In our submission adequate measures have not been taken to identify patients who might have been infected with Hepatitis C through blood and not identified through the look-back exercise.

⁴² [PEN.017.2307]

⁴³ Transcript 18/01/12 (Day 86): 75(16) to 76(8) (Dr Gillon)

⁴⁴ Transcript 17/01/12 (Day 85): 127(2-16) (Dr Alexander)

⁴⁵ Transcript 17/01/12 (Day 85): 127(4) to 128(8) (Dr Alexander)

In this regard it is evident that, despite the evident limitations of the look-back exercise, additional measures such as a meaningful publicity campaign were not undertaken.

In our submission, given that that the Inquiry has heard that the symptoms of liver disease usually appear 20 to 30 years after infection with Hepatitis C once a patient has developed cirrhosis⁴⁶, additional measures to raise public awareness about Hepatitis C could result in people who were missed by the look-back being identified.

Recommendations for the future

10. Lessons and implications that can be identified, and recommendations that can be made for the future, arising from the Inquiry's consideration of Topic C5b.

See joint recommendations for Topics B5 and C5

TOPIC C5c

The information given to patients who might have been infected, or who were found to be infected, and their families.

- 1. The manner in which positive tests results were communicated to patients (or their parents).**
- 2. When patients (or their parents) were advised of positive test results.**

There is evidence before the Inquiry from Professor Nathanson regarding the correct approach to communicating positive Hepatitis C test results to patients between 1991 and 2000.⁴⁷ In this regard there is an ethical requirement on doctors to ensure that information is given to patients in an appropriate way, Information must be contextualised and the doctor must explain what the information means to the patient and what will be done with the result. Furthermore, the doctor

⁴⁶ Transcript 11/10/11 (Day 52): 123(3-12) (Professor Thomas)

⁴⁷ [PEN.018.0419] at 0422 paragraph 3 read with [PEN.012.0330] at 0337 at paragraph 5 – reports by Professor Nathanson

is required to use his/her communication skills to help the patient understand the implications and to agree with the patient a plan of action.

The Inquiry has evidence that test results were sometimes communicated to patients in an unsatisfactory manner. For example, some patients were not told the results until they asked for them,⁴⁸ while others felt as though they were told in an off-handed way.⁴⁹ On the other hand the Inquiry has also heard about how arrangements were made for other patients to be told in the presence of a hepatologist to ensure that they received appropriate information and support when the diagnosis was given.⁵⁰

There is also evidence before the Inquiry indicating that there were delays in terms of when patients were tested and in this regard the Inquiry heard evidence that patients at Ninewells were not tested until late 1995.⁵¹ There also appear to have been delays informing patients of their diagnosis⁵². These examples illustrate the importance having protocols and guidelines in ensuring a consistent approach to the way in which patients are treated. In this regard it although there were guidelines available for doctors dealing with patients who were identified by the look-back, there do not appear to have been any equivalent guidelines for those treating patients with haemophilia.

3. The nature, extent and accuracy of the information provided to patients (or their parents) about the possible consequences of their Hepatitis C infection.

and

4. The manner in which information was provided to patients (or their parents) about the possible consequences of their Hepatitis C infection.

and

⁴⁸ Transcript 13/12/11 (Day 77): 21(11) to 22(3) (COLIN); Transcript 07/06/11 (Day 28): 18(4-12) (CHRISTINE)

⁴⁹ Statement of ELAINE'S brother-in-law: [WIT.004.0136] at paragraph 3; Transcript 14/12/11 (Day 78): 65(6) to 67(4) (Professor Hayes)

⁵⁰ STATEMENT OF ELAINE'S BROTHER IN LAW at paragraph 11

⁵¹ Transcript 13/12/11 (Day 77): 16(7-8) (COLIN) – Colin had been hospitalised for about ten days in 1994 during which time blood tests were done, but he was not tested for Hepatitis C; Statement of Core Participant: PI066MF at paragraph 10; Statement of Core Participant: PI055JP at paragraph 10

⁵² Preliminary Report, Chapter 4, 4.65 to 4.75

5. The extent to which patients (or their parents) understood the possible consequences of their Hepatitis C infection and whether communication of this information was adequate and effective.

In terms of what patients should have been told in relation to Hepatitis C, Dr Alexander told the Inquiry that in 1991 he would have told patients that it was thought that they had Hepatitis C but that the tests was not reliable, that they faced a chance of liver disease, which could not be qualified, and that they would be followed very carefully. If the patient wanted their partner or children tested this would be done, but the implications of a test result for either the partner or child would not be known at that point.⁵³ Dr Hayes pointed out how uncertainty about the natural history of Hepatitis C impacted on the counselling that was given to patients. Initially patients were told that it was a fairly benign condition for which NICE guidelines suggested that treatment was not necessary or available unless liver biopsy showed significant disease. This changed over the years from thinking that in the majority it was fairly benign to realising that large numbers of patients will go on to major complications, including cirrhosis and its complications.⁵⁴

It is apparent from the evidence of patients and their relatives that one of the main concerns shared by many of them is the lack of communication of information to them about the disease and its treatment by those treating them.⁵⁵ Patients felt as though they had little or no understanding of the disease and were left having to try to find out more about it on their own.⁵⁶

From the evidence it appears that relatively little was known about the disease at the time that many of the patients were diagnosed, and most of what was known about it related to its effects on the liver. It would appear that those treating patients with Hepatitis C might not have had much information to communicate to them at the time that they were diagnosed. However more has been learned since then about the disease, in particular about the extra-hepatic effects of Hepatitis C, and the Inquiry heard some evidence about this from Professor Thomas. It does not appear that any attempt was made to keep patients up to date with those developments.

⁵³ Transcript 17/01/12 (Day85): 143(4-14) Dr Alexander

⁵⁴ Transcript 14/12/11 (Day 78): 79(1) to 80(21) (Professor Hayes)

⁵⁵ Transcript 10/01/11 (Day 81): 28(17) to 29(13); 56(12-21) (ALEX); Transcript 13/12/11 (Day 77): 123(25) to 124(4) (GORDON); Transcript 15/12/11 (Day 79): 83(11) to 84(6), 87(16) TO 88(8). 90(4) TO 91(8) (ANNE);

⁵⁶ Transcript 09/12/11 (Day 76): 71(5-12) (BRIDIE); Transcript 10/01/11 (Day 81): 87(19-25) (ALEX); Transcript 13/12/11 (Day 77): 25(2-8) (COLIN);

6. **The nature and extent of the information provided to patients and their families about the risks of transmission of Hepatitis C and the precautions that should be taken to prevent transmission.**

and

7. **The extent to which family members of patients with Hepatitis C were offered testing.**

From the evidence before the Inquiry from patient and relative witnesses it is apparent there was inconsistency in terms of the information given to patients and their relatives about the risks of transmission. In relation to sexual transmission, some patients were advised that there was a risk⁵⁷ whereas others were not advised of any risk of sexual transmission.⁵⁸ In relation to other modes of transmission, some patients were not warned of any risks⁵⁹ whereas others were given some advice about precautions they could take.⁶⁰

It is also apparent from the evidence before the Inquiry from patient and relative witnesses that there was inconsistency in terms of whether or not the spouses and family members of patients infected with Hepatitis C were offered testing. In some cases testing was offered,⁶¹ in others the relatives were only tested after they asked for this, usually through their GP⁶² and in some cases no testing has ever been offered or done.⁶³

The Inquiry has heard evidence about guidelines that were available for the provision of information to patients who were identified through the look-back exercise, but there is no evidence for any such guidelines in relation to patients with haemophilia.

8. **The nature and extent of the counselling and support offered to patients infected**

⁵⁷ Transcript 09/12/11 (Day 76):48(13-14) (BRIDIE); Transcript 13/12/11 (Day 77): 23(5-7) (COLIN)

⁵⁸ Transcript 12/12/11 (Day 77): 124(5-21) (GORDON) although it appears that he and his wife were told within a few months; Transcript 15/12/11 (Day 79): 93(11-14) (ANNE); Statement of Core Participant: PJI199MF at paragraph 6; Statement of Core Participant: PI119JP at paragraph 13; Statement of Core Participant: PI017MF at paragraph 6 and of his wife PIO33MF at paragraph 5

⁵⁹ Transcript 09/12/11 (Day 76): 70(19) to 71(3) (BRIDIE); Statement of Core Participant: PJI199MF at paragraph 6; Statement of Core Participant: PI119JP at paragraph 13

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⁶¹ Transcript 13/12/11 (Day 77): 25(11-16) (COLIN); Transcript 10/06/11 (Day 31): 60(5-20)(ELAINE)

⁶²; Transcript 15/12/11 (Day 79): 7(22) to 8(12), 18(2-23) (LAURA); Statement of Core Participant: PJI199MF at paragraph 15; Statement of ELAINE's brother-in-law: [WIT.004.0136] at paragraph 13;

⁶³ Transcript 10/01/12 (Day 81): 45(2-7) (ALEX); Statement of Core Participant: PI056SC at paragraph 30; Statement of Core Participant: PI119JP at paragraph 17; Statement of Core Participant: PI066MF at paragraph 11

with Hepatitis C through blood and blood products, and to their families.

and

9. Differences between patients and doctors in terms of their understanding of the term “counselling”.

It is apparent from the evidence before the Inquiry from many of the patient and relative witnesses that there is a general feeling that very little was available to them in terms of counselling and support.⁶⁴ Given the devastating and wide ranging consequences that Hepatitis C infection and its treatment evidently have for patients and their families, they would clearly have benefited from additional support and counselling in terms of being able to come to terms with and cope with some of these consequences.

During the course of the oral hearings it became apparent that there is a difference between patients and medical practitioners in terms of what they understand by the word “counselling”. In this regard some of the patient witnesses did not consider that they had received any counselling while their medical records mention that counselling had been given.⁶⁵

In relation to how medical practitioners interpret the word “counselling”, Professor Nathanson explained that the word “counselling” refers to the very simple concept of giving patients enough information to make an informed decision.⁶⁶ Professor Hayes said that the word “counselling” was about giving advice and answering questions and explained that word “counselling” in relation to the care and treatment of patients with Hepatitis C meant providing information and support. By way of example he said that in Edinburgh it was thought sensible for haemophilia patients to be seen by a hepatologist or a liver specialist, rather than just the haemophilia specialists, so arrangements were made for him to see the patients at the same time as the haemophilia specialists and if they did not know that they had Hepatitis C then he would try to give them information about the natural history, the problems that they may or may not have, symptoms associated with the condition, risks of transmission and available treatments. He said

⁶⁴ Transcript 09/12/11 (Day 76): 18(19-23) (BRIDIE); Transcript 10/01/11 (Day 81): 30(18) to (31(3), 39(23) to 40(1), 45(24) (ALEX); Transcript 13/12/11 (Day 77): 125(5-7), 151(17-21) (GORDON); Transcript 15/12/11 (Day 79): 68(25) to 69(8) (LAURA); Transcript 15/12/11 (Day 79): 83(11) (ANNE); Statement of Core Participant: PI119JP at paragraph 17; Statement of Core Participant: PI066MF at paragraph 11

⁶⁵ Transcript 13/12/11 (Day 77): 20(3-7); 24(20) to 25(8) (COLIN); Transcript 09/06/11 (Day 30): 114(22-35) (DAVID); Statement of Core Participant: PI066MF at paragraph 11

⁶⁶ Transcript 12/01/12 (Day 84): 40(23) to 41(7) (Professor Nathanson).

that counselling would have changed over the years and as more information became available.⁶⁷

If it is the case that the “counselling” and support that is available to patients with Hepatitis C refers to information and support specifically in relation to liver disease, then this was clearly inadequate in terms of assisting patients in coping with the broader physical, mental, social and financial consequences of Hepatitis C infection. In our submission additional counselling and support, beyond merely providing information, should have been made available to patients and their relatives.

10. Lessons and implications that can be identified, and recommendations that can be made for the future, arising from the Inquiry’s consideration of Topic C5c.

See joint recommendations for Topics B5 and C5

⁶⁷ Transcript 14/12/11 (Day 78): 65(6) to 67(4) (Professor Hayes)