Issue 1:

Donor selection, donor testing, and tracing of blood donations in Scotland during the period 1974 to 1995

Topics covered:

B1 – The efforts made to discourage 'higher risk' donors from giving blood (by the dissemination of information, including leaflets); whether these efforts went far enough and began early enough.

C1 – The acceptance of blood from 'higher risk' donors, in particular:
(a) prisoners; and
(b) donors who had a history of jaundice, and who were negative for Hepatitis B when existence of Non-A Non-B hepatitis was known and its presence could not be excluded.

C2 – The non-introduction in Scotland of surrogate testing for non-A Non-B hepatitis.

B4 – The decision not to use kits from the United States of America for testing donated blood for the virus as soon as they became available but, instead, to follow a process of evaluation of the kits before any such use.

C4 – The interval between the availability of tests for the Hepatitis C virus in 1989 and the introduction of screening of donated blood for the virus in the United Kingdom in September 1991.

B5b) – The tracing and testing of patients who might have been exposed to the virus through their treatment with blood or blood products.

C5b) – The tracing and testing of patients who might have been exposed to the virus through their treatment with blood or blood products.

Topic B1

PENROSE INQUIRY

TOPIC B1

Evidence was given on this topic by:-

(1) Dr Brian McClelland (Day 12)

The relevant statements on this topic are:-

(1) Dr Brian McClelland WIT.003.0036 and WIT.003.0072
(2) Dr Ruthven Mitchell WIT.003.0033

SNBTS briefing papers relevant to this topic are:-

(1) SNBTS briefing paper on Actions taken by the SNBTS to Protect Patients from AIDS. SNB.014.3070
(2) SNBTS briefing paper on Donor Selection Policies and Procedures. SNB.014.3125

TOPIC B1

The efforts made to discourage "higher risk" donors from giving blood (by the dissemination of information, including leaflets); whether these efforts went far enough and began early enough

Topic B1 - Inquiry Counsel Issues Nos: 1 & 2

1. **Should steps have been taken in Scotland earlier than May/June 1983 to alert blood donors to the risk of transmitting AIDS via donated blood and to prevent higher risk donors from giving blood?**

2. **Were there other measures that should have been adopted but were not?**

- The SNBTS ensured, through its medical and scientific professionals, that the latest information was disseminated widely. For example, Dr Peter Foster had reported from the August 1982 meeting of the International Society of Blood Transfusion on the first presentation suggesting that patients with haemophilia may have contracted an AIDS like syndrome. The evidence shows the SNBTS was well informed and during the period 1983-84 made use of the best available knowledge in developing its response to AIDS[1,2,3,4].

- SNBTS started to work on donor selection within a few weeks of the publication of US Public Health Services (USPHS) Interagency Guidelines in March 1983. This document was the first attempt to classify "higher risk" donors for purposes of donor selection and it was based on the epidemiological information that had been accumulated in the United States where the epidemic had progressed much further than in the UK. The first SNBTS AIDS information leaflet for donors was deployed within 4 months of the release of the publication of the USPHS Interagency Guidelines[1,2,5]. These actions were timely and continued to be reviewed and amended in the light of the evidence that was emerging.

- In terms of taking relevant and useful action earlier, other witnesses[7,8] have given evidence that in early 1983 it had not been firmly established that AIDS was caused by an infectious agent. Various causes were being canvassed to explain the immunosuppression seen in AIDS patients and haemophilia patients. The communication of the first report of AIDS following a blood component transfusion in late 1982 made an infectious cause much more probable. This report provided the first strong evidence that measures to avoid taking blood from those who might pose an increased risk to recipients should be based on the assumption that a transmissible cause would be found. The publication of the US guideline was the first practical application of the available epidemiological information to donor selection. These guidelines were rapidly implemented by the SNBTS[1,2,6].

- The emergence of AIDS was a major factor in driving the move towards commonality in procedures across the UK. Donor selection procedures have for years been standardised among all the UK transfusion services and are published and updated on the website www.transfusionguidelines.org.uk and in paper form as the "Red Book" (Guidelines for the Transfusion Services in the UK), an initiative in which Professor Cash played a major part (Inquiry Transcript Day 12, page 4).

- To meet patients' needs, the SNBTS depended on volunteer donors. It was (and remains) essential to strike a balance between the use of intrusive investigation of donors' behaviour and the risk that it may reasonably discourage them from further volunteering.

  At this time the risks for AIDS were understood only in terms of sexual behaviour, geographical origin, and injection of blood during transfusion or the use of contaminated equipment for illegal drug use. Thus any approach to selection had to be based on these characteristics. In 1983, there were no reliable means of establishing a volunteering individual's sexual behaviour. (This remains true today.) Thus, some form of self identification was the only approach. Even direct questioning, which would have been unacceptably intrusive in 1983, offers no guarantee of reliable detection of risk behaviours. However, because it was felt that detection may be improved by this means, direct donor interviews were among the additional procedures progressively introduced by the SNBTS after 1983.

  Heat treatment of factor VIII proved to be an effective way of protecting haemophilia patients from HIV transmission. Taking into account concerns expressed by some clinicians that heat treatment might alter the FVIII molecule leading to problems with treatment, and considerable debate between the SNBTS and NBTS, it was introduced by the SNBTS very early, at the end of 1984, following the recognition of possible transmission of HIV by SNBTS Factor VIII[11,12,13,14], and evidence that HIV could be inactivated by heat treatment under conditions that SNBTS FVIII could withstand.

- In terms of donor selection, the actions taken during 1983 were already breaking new ground in terms of the inquisition of volunteer donors and were intended to take account of such evidence as was then available about the cause of AIDS and about the characteristics of individuals who may have had a raised risk of transmitting. There has been continuous development of the procedures employed to minimise the chance of donations being accepted from donors in higher risk categories. The SNBTS has consistently been proactive in this field and a major contributor to the development of donor selection systems for the UK Transfusion services[11,15,16].

- By mid or late 1983, a common approach to these donor selection issues was evolving across the UK. This reflected the awareness of the potential gravity of the risks of an epidemic of AIDS[17].

- The first leaflet introduced by the SNBTS was based on the best evidence available at the time (from North America) about the types of behaviour and other attributes that had been found to have some degree of

association with the development of AIDS. Equivalent epidemiological data was not available for the UK when the early versions of the leaflet were prepared and so the US information had to be used. Over the years evidence has accumulated to show that the rate of infection with a number of infective agents is substantially lower among donors than in the general population. This suggests that donor selection measures are effective in selecting a safer donor population.

- A patient who needs transfusion depends on there being a sufficient supply of safe and effective blood. The primary responsibility of the SNBTS was, and remains, to provide blood that is of good quality, including having the lowest achievable risk of transmitting infection and to ensure that it is available in sufficient quantity to meet patients' needs. There were of course concerns about embarking on enquiries about the sexual behaviour of volunteer donors on the grounds of basic courtesy, and especially because of concern that donors could be discouraged from attending if the selection process was felt too insensitive or intrusive. The challenge was then, and remains, to strike a balance between patient safety from transfusion transmissible disease, adequacy of blood supply, and the duty of care to volunteer blood donors. The SNBTS can be seen to have maintained an appropriate balance[18,19].

References

1. Actions taken by the SNBTS to protect patients from AIDS – September 2010 (SNB.014.3070)
2. B1 witness statement submitted by Dr DBL McClelland - 31.01.11 (sections 1, 1.2, 1.3) (WIT.003.0036)
3. Inquiry Transcript Day 12 (Dr DBL McClelland) pp 69-70
4. B1 witness statement submitted by Dr R Mitchell - 03.02.11 (WIT.003.0033)
5. Inquiry Transcript Day 12 (Dr DBL McClelland) – all
6. Inquiry Transcript Day 12 (Dr DBL McClelland) pp 10-16
7. Inquiry Transcript Day 18 (Professor Ludlam), page 117
8. Inquiry Transcript Day 17 (Professor Forbes), pages 96-97
9. Inquiry Transcript Day 12 (Dr DBL McClelland) pp 7-8
10. Penrose Inquiry Preliminary Report (para 5.22)
11. Donor Selection Policies and Procedures – September 2010 (SNB.014.3125)
12. Letter Prof Ludlam to J Watt 24.03.83 (SNB.006.4708)
13. Inquiry Transcript Day 44 (Professor Ludlam), page 9
14. BTS/SNBTS meeting at Elstree on 10th December 1984 (SNF.001.3850)
15. Inquiry Transcript Day 12 (Dr DBL McClelland) pp 10-23
16. B1 witness statement submitted by Dr DBL McClelland - 31.01.11 (sections 3, 4, 5, 13) (WIT.003.0036)
17. C1 witness statement submitted by Dr DBL McClelland - 31.01.11 (pp 2/3) (WIT.003.0072)
18. Transcript Day 12 (Dr DBL McClelland) pp 42-43
19. B1 witness statement submitted by Mr J Wastle – 03.02.11 para 5 (PEN.010.0316)

Topic C1

PENROSE INQUIRY

TOPIC C1

Evidence was given on this topic by:-

(1) Dr Brian Dow (Days 8 and 24)
(2) Dr Brian McClelland (Day 9)
(3) Dr Ruthven Mitchell (Day 9)
(4) Professor John Cash (Day 10)
(5) Dr John Gillon (Day 11)
(6) Dr Robert Perry (Day 11)
(7) Dr Graham Scott (Day 11)
(8) Professor Juhani Leikola (Day 13)

The relevant statements on this topic are:-

(1)	Dr Brian Dow	WIT.003.0094
(2)	Dr Brian McClelland	WIT.003.0072
(3)	Dr Ruthven Mitchell	WIT.003.0106
(4)	Professor John Cash	WIT.003.0120
(5)	Dr John Gillon	WIT.003.0129
(6)	Dr Robert Perry	WIT.003.0050
(7)	Dr Graham Scott	WIT.003.0019
(8)	Professor Juhani Leikola	WIT.003.0027
(9)	Dr Ewa Brookes	WIT.003.0057
(10)	Dr Archibald McIntyre	WIT.003.0013
(11)	Dr Iain Macdonald	WIT.003.0023
(12)	Mr John Wastle	WIT.010.0316

SNBTS briefing papers relevant to this topic are:-

(1)	SNBTS Blood Collection 1975-1991	SNB.014.3065
(2)	SNBTS briefing paper on Collection of Blood in Prisons	PEN.018.1521
(3)	SNBTS briefing paper on Hepatitis Risk Warnings.	PEN.012.0286

TOPIC C1

The acceptance of blood from "higher risk" donors, in particular:
(a) prisoners; and
(b) donors with a history of jaundice, and who were negative for Hepatitis B when the existence of Non-A Non-B Hepatitis was known and its presence could not be excluded

Topic C1 - Inquiry Counsel Issues Nos: 1 – 4

1. **What evidence, if any, was there during the 1970s and early 1980s that prisoners in Scotland were "higher risk" donors i.e. that their blood carried a greater risk of transmitting infectious disease, in particular NANBH, when compared with donors who were not prisoners?**

2. **What, if anything, ought to have been done, by whom and when, as a result of that evidence?**

3. **Should the collection of blood from Scottish prisons have stopped earlier and, if so, when and why?**

4. **If blood had not been collected from prisons in Scotland in the 1970s and early 1980s, (1) could a sufficient blood supply have been maintained and (2) to what extent is the incidence of post transfusion NANBH/Hepatitis C likely to have been reduced?**

Before addressing the specific questions, it may be helpful to contextualise matters.

Firstly, it is important to keep in consideration the proportion of the total donations which prison donations represented (see PEN.010.0026 discussed with Professor Cash on day 10, pages 8-12, and PEN.010.0003 also discussed with Professor Cash day 10, pages 13-20).

In short, it appears that between 1974 and 1984, in Scotland, the average percentage for prison donations in terms of overall donations in that period was 1.12%. Perhaps more significantly, the percentage appeared to decline over that period. In Glasgow and the West the percentage declined from a high of 2.83% in 1975 to a low of 0.23% when the practice ceased in 1984. Similarly in Edinburgh and South East Scotland the percentage declined from a high of 1.37% in 1975 to a low of 0.23% in 1981 when the practice ceased in Saughton, the only prison in that area from which donations were collected.

Secondly, it is necessary to have regard to (a) the improved reliability of testing for Hepatitis B with the introduction of RIA testing (although it seems that different RIA kits made by different manufacturers had different sensitivities - day 10, page 101), and (b) the extent to which it is or was legitimate to equiparate Hepatitis B with NANB Hepatitis. Whatever the conclusions that were or ought to have been drawn from the Wallace Paper (1972, SGH.002.9831) and the Barr Paper (1982, PEN.014.0068) the fact is that in the late 70s/early 80s there was a reliable test for the detection of Hepatitis B. As Dr Gillon put it, "I think the focus on prisons had been largely in relation to Hep B and the feeling was that testing had reached the level of sensitivity

that took that off the radar to some extent" - day 11, page 73. The question therefore was the possible similarity of the Hepatitis B virus to the as yet unidentified NANB virus. Dr Gillon spoke of how very infectious the Hepatitis B virus was, and how it was known by the mid 1970s that it was likely to spread in any sort of residential setting - see day 11, pages 70-71. In contrast it appears that very little was known about the prevalence or the effect of NANB Hepatitis - see Dr Gillon, day 11, page 75-76 and also Dr Mitchell at day 9, page 165-6.

By the early 1980s what had been demonstrated was that screening for Hepatitis B resulted in a five fold higher incidence found in prisoners compared to non prison donations SGH.002.9831. These Hepatitis B positive detected donations were removed from the blood supply and as a result of improvements (mainly a logarithmic increase in sensitivity) in Hepatitis B screening in the mid 1970s, the incidence of reported cases of post transfusion Hepatitis fell dramatically - PEN.013.0398.

It is against the above that the questions require to be addressed.

The Wallace, Barr, Prince (LIT.001.0363), Hoofnagle (LIT.001.3657) and Berman (LIT.001.0189) papers represented accumulating evidence that there was a problem but significantly in the context of individuals who were apparently not experiencing symptoms to any great extent and who had no physical evidence of chronic liver disease. The description in Professor Sheila Sherlock's textbook "Diseases of the Liver and Biliary System" in 1983 of NANB Hepatitis was that it was essentially benign.

It is questionable how much reliance can be placed on these articles as a basis for any proposition that collection from prisons ought to have ceased earlier. For the record the last prison sessions were:-

North East (Aberdeen) - Peterhead Prison, 28th July 1983
East (Dundee) - Perth Prison, 2nd August 1983
South East (Edinburgh) - Saughton Prison, 22nd December 1981
West (Glasgow) - Glenochil Young Offenders Institution, 25th March 1984
North (Inverness) - Porterfield Prison, 24th February 1983

- see PEN.010.0012

It is clear that the decision to stop was not a national decision. The matter was discussed at a meeting of regional directors on 29th March 1983 (minutes - SGF.001.0234) when it appeared that consensus could not be reached - see Professor Cash, day 11, pages 40-46. By that time two centres, i.e. North (Inverness) and South East (Edinburgh) had already stopped. North East (Aberdeen) and East (Dundee) stopped four and five months later. It was Dr Mitchell from Glasgow who was concerned about the effect cessation would have at traditional periods of low supply e.g. the Glasgow Fair but in evidence stated that by the end of 1983 he took the decision to withdraw. His constituency of course took donations from eight institutions with sessions booked well in advance - day 9, page 161-162. His reason for stopping however had nothing to do with Hepatitis B and it will be recalled that he was one of the co-authors of the 1981 Barr Paper (see day 9, page 157), but rather the growing concerns arising during the course of 1983 in relation to AIDS.

On the question of whether collection from prisons should have ceased earlier, it is, it is submitted, something of an exercise in hindsight so to suggest. Professor Leikola's view appeared to be encapsulated at paragraph 16 of his report

WIT.003.0027, i.e. that it would have been reasonable for Scotland to reconsider the practice. He seemed to accept that his view was largely informed by the fact that Finland had stopped in 1975 following the publication of Dr Helske's doctoral thesis published not in a regular issue but in a supplement to the Scandinavian Journal of Haematology - day 13, page 102. Standing that nothing was written on the question of prison donations in any international guidelines before 1983, that prisoners were not included in the definition of "high risk" donors in any of the Council of Europe recommendations in 1980-1981 or 1983 (the last partly drafted by Professor Leikola) and that the first unequivocal guidance from any regulatory body in the world was that of the FDA in 1995, it is suggested that it is something of an exercise in hindsight to say that collections in Scotland should have ceased earlier.

It is submitted that it is important to consider the likely result of earlier cessation. In this regard the evidence of Dr Perry on day 11, page 120-121 is informative, i.e. "that even if it were the case that there was a higher risk of infectious disease, particularly NANB - this is in the earlier 80s - from prison donors, removing that source of plasma from the supply to PFC would not have made a difference to the safety of the products that we were manufacturing, and the reason for that is that the - our belief at the time was that the background level of NANB Hepatitis in the 1980s was roughly, I think, from memory, 0.5% or some figure around that. So even if we removed a few donations by removing prison donors, each pool of plasma that was used to make the clotting factor products, the Factor VIII and Factor IX would still have been contaminated from the infective donations which were in the general blood donor pool".

On the question of whether a sufficient blood supply could have been maintained, Dr Mitchell suggested that the loss of prison donations particularly at holiday periods may have resulted in serious blood shortages - WIR.003.0079 and day 9, page 162. Edinburgh and South East appear to have had no particular problems regarding maintaining adequate blood stocks - WIT.003.0122.

The final question in relation to the cessation of collection of blood from prisons must be that of who should have taken the decision. It is clear that in effect the regional directors took the decision themselves and that there was little or no debate within SNBTS although Professor Cash was fully aware of the need to debate the issue.

There was a stark contrast between the evidence of Dr Graham Scott (day 11) who emphatically refused to even entertain the idea that the responsibility lay other than with the regional directors and repeatedly stated that it was a clinical matter. Professor Cash and Dr Mitchell thought otherwise. Professor Cash spoke of how he had "inherited a service in which the Department of Health in London dictated the whole business of donor selection" - day 10, page 39. Dr Mitchell also expected some guidance - day 9, pages 160-161.

That there was a policy was clear from the DHSS letter of 1st May 1975 (SGH.003.0187). That SHHD were aware of such a policy is also clear - see SHHD Memo 11th August 1983 SGH.001.0572, file note SGH.001.0571 and Minute of 6th May 1983 SGH.002.6764. While it is true to say that directors were capable of making a decision on clinical grounds to cease (and indeed did so), this is only part of the story. There were, it is submitted, wider social policy considerations that the SHHD, whose representatives sat in on the Regional Centre Directors' meeting and were aware of the debate, could have considered and acted upon if it had felt it appropriate to do so.

In conclusion therefore (i) there was no evidence before the Inquiry to show that the use of prison donations was a greater risk to patients than non prison donations and (ii) removing the small percentage of prison donations from the supply of plasma to the PFC would not have made any difference to the safety of the concentrates produced by the PFC in the late 1970s/early 1980s.

Topic C1 – Inquiry Counsel Issues Nos 5 – 8

5. **What evidence, if any, was there during the 1970s and 1980s that donors with a history of jaundice were "higher risk" donors i.e. that their blood carried a higher risk of transmitting infectious disease, in particular, NANBH, than donors with no history of jaundice?**

6. **What, if anything, ought to have been done, by whom and when, as a result of that evidence?**

7. **During the 1970s and 1980s should the SNBTS have refused to accept blood from donors with any history of jaundice (rather than simply refusing donors with a history of jaundice in the 12 months prior to donation) and, if so, why?**

8. **If, in the 1970s and 1980s, the SNBTS had rejected blood from donors with a history of jaundice, (1) could a sufficient blood supply have been maintained and (2) to what extent is the incidence of post transfusion NANBH/Hepatitis C likely to have been reduced?**

- The UK Transfusion Services had permanently deferred donors with a history of jaundice until the Maycock Report of 1975 (1), which was adopted formally into the Guidelines for the UK Transfusion Services in 1977 (2). No evidence was provided to the Inquiry as to how or precisely when the decision to rescind the ban on such donors was reached in the SNBTS, but evidence was presented showing that practice within the UK from 1975 was in line with all international guidelines (3), including a report from the WHO published in 1978 (4).

- It was stated in evidence that the relaxation of the ban was due to the emergence of tests for hepatitis B, which was the main concern for transfusion services until that time. NANB hepatitis was first described in 1974/5, and papers were cited which supported the view that this newly emerging type of post-transfusion hepatitis was only rarely associated with jaundice (5,6,7,8) (p 64 of Day 9 transcript), and that this consideration would have contributed materially to the continued acceptance of such donors, though the policy in the SNBTS was amended in the early 1980s to accept only those donors whose jaundice occurred before age 12, based on research carried out in the West of Scotland BTS (WBTS) (9).

- The WBTS research indicated that 2.8% of donors gave a history of jaundice. Calculations were provided to the Inquiry which related the potentially serious loss of around 10,000 donations annually to the effect on the incidence of PT NANB. The paper by Crawford et al (10), describing the epidemiology of donors with positive tests for hepatitis C following the introduction of testing in 1991, allowed retrospective calculation, based on the finding that 5.9% of these donors gave a history of jaundice. Taking the prevalence given in Crawford et al, and acknowledging the approximate nature of these hindsight-based calculations, it was suggested that around 15 cases of PT NANB might have been prevented annually in the second half of the 1980s (11). It was pointed out that the loss of donations would have a cumulative effect, as

potentially each donor could donate up to 3 or 4 times a year, and furthermore that the gap would have to be filled by increasing new donor recruitment, which in itself introduces an element of risk. The potentially adverse psychological impact on rejected donors, the vast majority of whom were not carriers of HCV, was also described as a consideration that had to be taken into account.

- Continuation of the policy to accept donors with a history of jaundice, with the later revision of restricting this to jaundice before the age of 12, took full account of knowledge derived from research in the WBTS and overseas, and was compliant with all guidelines applicable in the UK.

References

1. SGH 0030079
2. SNB0025348
3. Day 9 transcript (Dr B McClelland)
4. LIT0013627
5. LIT0010189
6. Hoofnagle et al, 1977, Transmission of Non-A Non-B hepatitis. LIT.001.3657
7. Chaudhuri, Chin and Follett, Viral Hepatitis in Glasgow 1976-1977. PEN.002.0511
8. Galbraith et al, 1975, Chronic Liver Disease developing after outbreak of HbsAG-Negative Hepatitis in Haemodyalysis Unit. PEN.013.1426
9. Barr et al, 1982, Blood donors with a history of jaundice. PEN.014.0067
10. Crawford et al 1994, Prevelance and epidemiological characteristeics of hepatitis C in Scottish blood donors. SNB.008.2088
11. WIT 00301229, and transcript, Day 10

Topic C2

PENROSE INQUIRY

TOPIC C2

Evidence was given on this topic by:-

1. Dr Brian McClelland (Days 63 and 64)
2. Professor John Cash (Day 64)
3. Dr Ruthven Mitchell (Day 65)
4. Dr John Gillon (Day 65)
5. Mr Duncan Macniven (Days 65 and 74)
6. Dr John Forrester (Day 66)
7. Dr Iain MacDonald (Day 66)
8. Dr Brian Dow (Day 67)
9. Professor Juhani Leikola (Day 71)

The relevant statements on this topic are:-

(1)	Dr Brian McClelland	PEN.017.0754 and PEN.017.2651
(2)	Professor John Cash	PEN.017.1741
(3)	Dr Ruthven Mitchell	PEN.017.1897 and WIT.003.0116
(4)	Dr John Gillon	PEN.017.1931
(5)	Mr Duncan Macniven	PEN.017.2053
(6)	Dr John Forrester	PEN.017.1752
(7)	Dr Iain MacDonald	PEN.017.1702
(8)	Dr Brian Dow	PEN.017.1925
(9)	Professor Juhani Leikola	PEN.017.1837

SNBTS briefing paper relevant to this topic is:-

(1)	SNBTS briefing paper on Actions taken by the SNBTS to Protect Patients from AIDS	SNB.014.3070

TOPIC C2

The non-introduction of surrogate testing for Non-A, Non-B Hepatitis

Inquiry Counsel Issues Nos: 1 – 5

1. **Why was surrogate testing not introduced in Scotland in the second half of the 1980's, in particular, after the SNBTS Directors recommended at their meeting on 3 March 1987 that such testing should be introduced from 1 April 1988?**

2. **Should surrogate testing have been introduced in Scotland in the second half of the 1980's?**

3. **What was the state of medical and scientific knowledge regarding post-transfusion NANBH in the second half of the 1980's, in particular, in respect of its' clinical significance and likely prevalence in Scotland? To what extent did that state of knowledge influence, or ought to have influenced, the consideration of whether surrogate testing should be introduced?**

4. **To what extent did the strict liability provisions of the Consumer Protection Act 1987 influence, or ought to have influenced, whether surrogate testing was introduced?**

5. **If surrogate testing had been introduced in Scotland in the late 1980s, (1) could donor counselling have been satisfactorily addressed, (2) could a sufficient blood supply have been maintained and (3) to what extent is the incidence of post transfusion NANBH/Hepatitis C likely to have reduced?**

- North American observational studies [PEN.017.0870] [PEN.017.0930] [LIT.001.0753] [LIT.001.3755] suggested that surrogate testing might be useful in reducing hepatitis in transfusion recipients. However it was acknowledged by the authors of these studies that their observations did not allow a prediction of the actual effectiveness of such testing. This would require a prospective, randomised study. During the early 1980's SNBTS promoted the importance of performing a prospective trial to test the impact that surrogate testing might have on the incidence of non A non B hepatitis following transfusion [PEN.017.1514], [PEN.017.1486] but this did not receive sufficient professional support in the UK to proceed. Evidence has been presented that one factor contributing to the fact that a UK prospective trial of surrogate testing was not carried out was the experience of an earlier trial conducted for the UK Medical Research Council and published in 1974, and the published interpretation of its findings which were taken to show that the risk of non A non B hepatitis was low [day 63 (Dr DBL McClelland) pp 12-30].

  There was a quite widely held contrary view that surrogate testing would offer little or no improvement in donor safety. Indeed, SNBTS itself published research findings from a study on blood donors that added substantially to a body of data showing that "positive" surrogate tests could be caused by many conditions, raising serious questions about the

specificity of such tests for a supposed infectious form of hepatitis [LIT.001.1857]. This was an example of many reports indicating that the finding of elevated levels of a liver enzyme such as ALT in the blood was a non specific finding.

The issues to be resolved in relation to surrogate testing were that the patient requiring transfusion (a) needed blood to be available in sufficient quantity and (b) needed blood of good quality, including having the lowest achievable risk of transmitting an infection. If a new test were to result in the loss of many donors, resulting in insufficient supplies, this would affect the patient's interests. In addition, transfusion services have a duty of care to those who volunteer to donate. Part of this is to avoid as far as possible causing harm to the donor that may result from the assignment of a positive test result, whether true positive or false positive. It remains to this day a challenge for transfusion services to strike a correct balance.

Notwithstanding the above, in 1987 and before the emergence of a specific hepatitis C test, SNBTS proposed that surrogate testing be introduced without further delay since the time for a further trial had passed. [SGH.002.8101]

- At the times when the decision was relevant, the level of uncertainty was such that a decision not to undertake surrogate testing appears rational. Even with hindsight, the question of whether a sufficient blood supply could have been maintained and to what extent the incidence of post transfusion NANBH/Hepatitis C may have been reduced, is not answerable. Evidence has been provided to the Inquiry to the effect that the published results of the only known prospective trial of surrogate testing [PEN.017.0864] do not allow any conclusion to be drawn about the effect of surrogate testing on the risk of non A non B hepatitis in transfusion recipients. The authors of the paper describing this trial drew the conclusion that testing would have provided a considerable reduction in risk, but statistical opinion presented to the Inquiry does not endorse that interpretation of the data [PEN.019.0100].

  Neither is it clear that sufficient evidence was ever available from other countries to allow a reliable judgement to be made of the effectiveness – in other settings - of surrogate testing on the incidence of non A non B hepatitis following transfusion. It is notable that Professor Leikola did not support the introduction of surrogate testing in the UK [PEN.017.1837]. Attempts in 2011 by SNBTS to obtain further information from the German Red Cross met with no success [PEN.017.2667].

- The opinion has been expressed to the Inquiry that there was a quite widely belief held in the UK that non A non B hepatitis following transfusion was a much less significant problem in the UK, with its entirely voluntary donor system than in the United States where substantial numbers of donations had been obtained from paid "donors". It is difficult or impossible to judge now (a) whether this view of beliefs in the early 1980's is correct, and (b) if such a belief was prevalent, the extent to which it may have influenced decisions about testing donors [PEN.017.0754 pp 1-3] [day 63 (Dr DBL McClelland) pp 2-23]

  Responsibility for professional advice rested largely with transfusion specialists, including those in SNBTS, clinicians and virologists. Policy

decisions that involved the expenditure of public funds lay with the relevant Government departments. Decision making about surrogate testing would have been influenced by conflicting professional opinions, the lack of hard evidence about both, the impact of testing on patient safety, and concern that introduction of surrogate testing could have an important adverse effect on the availability of blood. This professional uncertainty was reflected in the advice given to Health Department civil servants in both Scotland and England.

Topic B4

PENROSE INQUIRY

TOPIC B4

Evidence was given on this topic by:-

(1) Professor John Cash (Day 48)
(2) Professor Robin Weiss (Day 48)
(3) Professor Richard Tedder (Day 49)
(4) Dr Graham Scott (Day 49)
(5) Dr Brian McClelland (Day 50)
(6) Dr Ruthven Mitchell (Day 51)

The relevant statements/reports on this topic are:-

(1)	Professor John Cash	PEN.017.1038
(2)	Professor Richard Tedder	PEN.017.1831
(3)	Dr Graham Scott	PEN.017.0513
(4)	Dr Brian McClelland	PEN.017.1337
(5)	Dr Ruthven Mitchell	PEN.017.1002
(6)	Dr Brian Dow	PEN.017.1680
(7)	Dr Phillip Mortimer	PEN.017.1761

TOPIC B4

The decision not to use kits from the United States of America for testing donated blood for the virus as soon as they became available but, instead, to follow a process of evaluation of the kits before any such use

Topic – B4 Inquiry Counsel issues Nos: 1- 4

1. **Whether it was necessary to conduct evaluation of the kits before introducing them into screening of donated blood in Scotland.**

2. **Why was it not considered necessary for the kits to have the approval of the US Food and Drugs Administration for use in the United States of America before introducing them for screening of blood in Scotland?**

3. **Whether an evaluation exercise in Scotland, such as that proposed by Professor Cash, would have led to the introduction of screening earlier than October 1985.**

4. **If so, why did such an evaluation not take place?**

- In the late 1970s, the UK blood services gradually replaced "in-house" developed assays with commercial test systems. Regardless of origin, any potential test system had to be evaluated to assess the kit's performance on known positive and negative materials to give an assessment of sensitivity and specificity respectively. The introduction of blood donation anti-HIV testing by the SNBTS and the other UK Blood Transfusion Services was dependent on the use of commercial test kits (Preliminary Report 8.126-7) and the EAGA was the committee that advised the DHSS/SHHD about these issues. The evaluation of these kits to determine that they were sufficiently sensitive, specific and robust for use by the UK Blood Transfusion Services was carried out by the Public Health Laboratory Service (PHLS) in London (Colindale). These evaluations concluded that the kits (e.g. Abbott) available from the United States of America were not suitable for blood donor screening purposes. This left the UK blood services with a choice of only two kits, namely the Organon Vironostika assay (manufactured in the Netherlands) and the Wellcome Diagnostics Wellcozyme assay (manufactured in the UK) (Preliminary Report 8.134). Following a limited local evaluation of both these assays in the late summer of 1985, the SNBTS along with the other UK Blood Transfusion Services introduced HIV testing in October 1985 as soon as sufficient stocks had been established by the commercial manufacturing companies. It should be emphasised that there was no delay in the completion of the UK test kit evaluation. The first phase of testing had been conducted entirely within PHLS Colindale with further local familiarisation of the two "approved" test systems completed within a few months. The selected commercial companies required a few months to ramp up manufacture in readiness for the UK "go-live" date. All SNBTS regions began donor screening using the Wellcozyme assay (PEN.017.1680).

Outwith the SNBTS, the NHS microbiology laboratories, in particular the Scottish HIV reference virology laboratories at Ruchill, Glasgow and University of Edinburgh Medical School had both instigated HTLV-III research into developing tests by early 1985 and both had experience of the early Abbott HTLV-III assay at that time.

- United States FDA approval of kits was essential for all commercial kits that were to be used within the American market (PEN.017.2500). However the use of European manufactured test systems (such as Wellcome or Organon) would not have required FDA approval unless these kits were to be marketed in the USA. Therefore in the UK, it was not an essential requirement for any potential test system (PEN.017.2115). Regardless of tests having FDA approval, it is necessary to evaluate any potential test to determine if the test is suitable for the population that it is to be used on. In addition, it is normal when evaluating a test system to assess robustness, sensitivity and specificity to check the claims of the manufacturer.

- The evaluation exercise in Scotland, as proposed by Professor Cash in early 1985, would not have been able to test many known confirmed HIV positive samples, as these samples were then either not available for SNBTS evaluation or only accessible to the NHS diagnostic laboratories (e.g. PHLS Colindale, or later the HIV Reference Laboratories at Ruchill or Edinburgh Medical School).

  A decision to use US manufactured tests as soon as they were available would have resulted in many normal healthy blood donors being rejected as “false positives” (PEN.017.1684; PEN.017.1761). To have introduced such a test without an evaluation process would have resulted in a significant loss of donations reducing the blood supply with obvious potential effect on patients. The need to evaluate before the introduction of routine testing allowed sufficient confidence to be generated to ensure that any potential test had all the necessary qualities (robustness, sensitivity, specificity, etc).

- In addition, the Glasgow transfusion centre did perform a limited local evaluation. Also once routine donor screening had commenced using the UK manufactured Wellcozyme kit, a parallel evaluation was conducted of the US manufactured Abbott HIV (HTLV-III) assay. This parallel evaluation showed that the Abbott test kit had relatively poor specificity with many false positive results (PEN.017.1684).

Topic C4

PENROSE INQUIRY

TOPIC C4

Evidence was given on this topic by:-

(1) Dr Brian Dow (Day 67)
(2) Dr Robert Perry (Day 68)
(3) Dr Brian McClelland (Day 70)
(4) Mr George Tucker (Day 69)
(5) Dr Ruthven Mitchell (Day 69)
(6) Mr David McIntosh (Day 70)
(7) Professor Juhani Leikola (Day 71)
(8) Professor John Cash (Days 72 and 82)

The relevant statements/reports on this topic are:-

(1)	Dr Brian Dow	PEN.017.1915
(2)	Dr R Perry	PEN.017.2108
(3)	Dr Brian McClelland	PEN.017.2491
(4)	Dr R Mitchell	PEN.017.1901
(5)	Mr George Tucker	PEN.017.2060
(6)	Mr David McIntosh	PEN.017.2126
(7)	Dr Archibald McIntyre	PEN.017.2073
(8)	Dr A B Young	PEN.017.2071
(9)	Sandra Falconer	PEN.017.2120
(10)	Mr Roderick Angus	PEN.017.2084
(11)	Mr David Hogg	PEN.017.2146
(12)	Professor J Leikola	PEN.017.1957 and PEN.017.1961
(13)	Professor J Cash	PEN.017.2094 and PEN.017.2779
(14)	Lord Forsyth of Drumlean	PEN.017.2799

There is also the Inquiry team's "extended narrative" document which is PEN.017.2165.

TOPIC C4

The interval between the availability of tests for the Hepatitis C virus in 1989 and the introduction of screening of donated blood for the virus in the United Kingdom in September 1991.

Inquiry Counsel Issues no 1 – 8

1. **When it became apparent in 1988 that tests for the hepatitis C virus were shortly to become available, was there a satisfactory mechanism for determining whether these tests should be introduced for the screening of donated blood in Scotland?**

2. **When it became apparent that the introduction of screening for hepatitis C might be recommended, was there a satisfactory mechanism for determining when and how the introduction of screening in Scotland would be effected?**

3. **Whether the existence of two groups with similar remits (ACVSB and ACTTD) impeded decision-making.**

4. **The factors which contributed to there being no decision to recommend to Ministers that screening should start as soon as practicable until November 1990.**

5. **Why was there a delay of almost ten months between the decision by ACVSB on 21 November 1990 to recommend the introduction of screening as soon as practicable and the introduction of screening in Scotland on 1 September 1991?**

6. **Whether, during this period, the involvement of the Health Minister earlier than July 1991 would have led to earlier introduction of screening.**

7. **The formulation of policy regarding the co-ordination of the starting date for the introduction of screening in Scotland with the starting date for England and Wales, the flexibility of such policy and whether such policy as existed resulted in delay in the introduction of screening in Scotland.**

8. **The relevance to the decision-making process of the Consumer Protection Act 1987, and the relevance for the consideration of this Inquiry of the decision in A v National Blood Authority [2001] 3 All E R 289.**

Governance, policy and decision making

Questions 1 - 3 in the List of Issues proposed by Inquiry Counsel concern the fundamental questions of the governance of decision making around the introduction in Scotland of screening of donated blood for Hepatitis C and raise the important question of which body was, or should have been responsible for decisions of this sort and the implementation of those decisions.

Responsibility for advising government departments on the evolving science and technical developments around the virological safety of blood (including the discovery of the Hepatitis C virus and tests to identify the virus in blood) rested with the Advisory Committee on the Virological Safety of Blood (ACVSB). Otherwise known as the "Metters" Committee (formerly the "Harris Committee"), the ACVSB was set up in response to an expectation of imminent developments in blood safety which UK Ministers wished to introduce in a coordinated UK manner. It was considered that the existing Expert Advisory Group on AIDS (EAGA), which had been set up in 1985 to provide UK Health Departments with expert advice on AIDS related matters, was not the appropriate body to provide expert advice regarding Hepatitis C or other related matters concerning the virus safety of blood. Evidence concerning the role and purpose of the ACVSB, and the purpose of the Advisory Committee on Transfusion Transmitted Diseases (ACTTD), which took a more practical role than the ACVSB, is conveniently set out in Dr McClelland's statement at PEN.017.2491. See also the discussion at the meeting of the ACVSB on 24th April 1990 at paragraph 32 (SNB.001.9761).

Examination of the minutes of ACTTD which met prior to the introduction of Hepatitis C screening in 1991 on 24th February, 19th May, 9th October and 22nd November 1989, only once during 1990 on 16th March 1990, and four times in 1991 on 8th January, 25th March, 10th June and 13th August, and also those of the ACVSB which met on 4th April, 22nd May, 3rd July and 6th November 1989, 17th January, 24th April, 2nd July and 21st November 1990 and on 25th February and 21st May 1991, reveal that the questions of whether to introduce screening, and when, were clearly considered by both officials and expert members of the committee to be the responsibility of the ACVSB. Further, the minutes of the SNBTS Directors' meeting on 13th December 1988 reveal that the purpose of the ACVSB was to "advise the UK Departments of Health on policies". There was, therefore, a UK structure for the governance of transfusion safety developments concerning Hepatitis C, and other issues, during the years 1988 to 1991 which was clear to all those involved in advising and decision making. There was also, in Scotland, no difficulty or confusion regarding relative responsibilities of the SNBTS and Government, nor any difficulty with the funding of such developments. There is also no evidence that the existence of the two advisory bodies, the ACVSB and the ACTTD, impeded decision making, either in nature or timing. Indeed the evidence presented to the Inquiry suggests that, despite a degree of 'territorial confusion', the activities of both groups were complementary in taking new safety developments through the various phases of policy guidance and practical operational implementation.

Any scheme which requires to be funded by a government department requires Ministerial approval. Therefore, in terms of Ministerial involvement in decision making around the introduction of Hepatitis C screening, it is axiomatic that the decision was ultimately one for the relevant Minister. In Scotland, and in England and Wales, the ACVSB was the committee set up to advise the relevant government departments. Evidence of its UK wide role and authority derives from the observation that the committee was regularly attended by officials from Scotland, Wales and Northern

Ireland Health Departments. The responsibility for the introduction of donor screening was therefore that of the relevant Minister of Health, suitably advised by the ACVSB and there is evidence before the Inquiry of early Ministerial involvement in the issue (PEN.017.2799).

It is important to recognise that, within the system described above, there was little, if any, freedom for the SNBTS to act outwith the guidance and policies developed by the ACVSB and communicated via Health Departments. Nevertheless, the SNBTS knew where it stood. It fulfilled its responsibilities around the introduction of Hepatitis C screening, including being aware of scientific developments around HCV and testing for the virus, putting itself forward to participate in scientific evaluations of testing kits carried out at a UK level, taking an active part in discussions regarding practical advances in testing and responding promptly to directions from Government.

In terms of policy for the introduction of Hepatitis C screening, a clear policy was in evidence from the outset of consideration of the issue - that such introduction would be on a UK wide basis, on a single date to be determined, and on the basis of advice from the ACVSB. There were a number of witnesses who gave evidence as to the reasons for this policy having been adopted and its appropriateness in the context of the time. Additionally, there was precedent in the UK of the successful introduction of donor screening for HIV in 1985, across the whole of the UK, on a single date.

In terms of the make up of the ACVSB, there was much evidence presented to the Inquiry that the committee included some of the most eminent clinicians and scientists in the UK, who had an interest and expertise in the virological safety of blood. It contained representatives across a number of relevant specialities, and included appointments of both a very senior transfusionist, Dr Mitchell, and a fractionator, Dr Perry, from Scotland. Importantly in terms of communication of discussions and decisions of the committee directly to the government in Scotland, a medically qualified representative from the Scottish Home and Health Department was present as an observer at the ACVSB meetings, as was the case for Wales and Northern Ireland. From a Scottish perspective, and notwithstanding the presence on the ACVSB Committee of Dr Mitchell and Dr Perry from PFC (with Dr McIntyre of SHHD as an observer), it is difficult to avoid the conclusion that the committee was perhaps understandably anglo-centric. Dr Perry's evidence was that he and Dr Mitchell attended committee meetings in their individual medical and scientific capacities, and not as representatives of their organisations. Therefore, the SNBTS was not represented on the ACVSB as an organisation. Noteworthy is Dr Perry's evidence about the dissemination of information to SNBTS by Dr McIntyre of SHHD (day 68, page 18). There was apparently no means by which SNBTS could influence the agendas for the ACVSB meetings or submit briefing papers. See statement of Professor Cash (PEN.017.2094 at page 1 and his evidence on day 82 at page 129). Although there was an ethos of confidentiality within the committee, the evidence was that both Dr Perry and Dr Mitchell were able to advise SNBTS colleagues of the ACVSB discussions (but not to copy minutes to them).

In specifically addressing the first two questions proposed by Inquiry Counsel, the answer appears to be that there was no separate mechanism for looking at the issue of the introduction of screening for Hepatitis C in Scotland as distinct from the UK as a whole. It is quite clear that although there was a Blood Transfusion Service and a Fractionation Centre in England on the one hand, and an SNBTS and a Fractionation Centre in Scotland, matters of blood safety policy were applied on a UK wide basis, this being a primary reason for establishing the ACVSB. In the climate of the time, and in particular in the absence of formal regulatory systems for blood transfusion

services, that is perhaps entirely understandable. There was an assumption that on this, as on other such matters, the DHSS (which had no separate "Scottish branch") would take the lead. As Mr Tucker explained in his statement (PEN.017.2063), it was intended that the position reached around Hepatitis C would be a UK wide one. In this regard see also his evidence on day 69 at pages 102-106. See also Dr McIntyre's statement at paragraphs 10 and 13 at PEN.017.2074 and 2075 and his note of the ACVSB meeting on 21st November 1990 (SGH.002.8501). See also the statement of Roderick Angus at paragraphs 5 and 6 (sic) PEN.017.2085 and 2086; the statement of David Hogg at paragraph 13 of PEN.017.2147 and also the statement of Professor Cash at paragraph 13 of PEN.017.2094 at 2098 and 2099 and also his evidence on day 72 pages 125-127. See also Dr Perry's statement PEN.017.2108 at 2113 and his evidence on day 68 at pages 36 and 38.

Events during 1990 and 1991

As stated, the making of a recommendation for the introduction of donor screening was the responsibility of the ACVSB. Throughout its considerations of HCV testing, the ACVSB (or at least its Chairman and DOH) had evolved three main criteria to be satisfied prior to a recommendation being made to introduce testing, which were designed to balance the interests of both donors and patients following the introduction of testing. These were:

1. Evaluation and validation of candidate tests in the UK
2. Availability of suitable confirmatory tests, given the known and unacceptably high levels of false positive results from routine screening tests
3. Licensure of the test in its country of origin (i.e. the US)

There were clearly differences of opinion amongst the members of the ACVSB on the achievement of these criteria. At the sixth meeting of the ACVSB on 24th April 1990 (minutes SNB.001.9761) it appears that Dr Perry, Dr Gunson and Dr Zuckerman were in favour of a recommendation in principle for the introduction of donor screening, but that the majority view was to await the result of the comparative evaluation of both the Ortho and Abbot tests. At a subsequent meeting on 21st November 1990, the decision of the ACVSB was to start donor screening as soon as practicable, and it appears from Dr McIntyre's note that an introduction date of 1st April 1991 was discussed.

Consideration by the ACVSB was taking place against a constantly evolving and international scientific and practical background and, notwithstanding the views of Dr Perry, Dr Gunson and Dr Zuckerman at the ACVSB meeting in April 1990, there has been no evidence presented to the Inquiry of an advocacy for a recommendation of introduction of testing to have been made prior to the ACVSB decision to do so in November 1990. It would appear therefore that the role and authority of the ACVSB in making recommendations was universally understood and accepted by all stakeholders. It also follows that there was little, if any, scope or mechanism for counterproposals.

Notably during this period, there has been extensive evidence submitted to the Inquiry (by Dr Perry, Professor Cash, Dr McClelland, Dr Dow and in the SNBTS briefing paper on Hepatitis C) on the actions and contributions which the SNBTS

made to the UK discussions, evaluations and operational planning to ensure that the SNBTS was ready to implement testing following a decision by Government to do so. It is reasonable to conclude that, whatever the reasons for the delay in the UK introduction of HCV testing between November 1990 and September 1991, the SNBTS was not a causative factor.

Examples of the activities in which the SNBTS was involved include:-

a) Professor Cash arranged for sufficient kits of the original (first generation) Ortho HCV assay in the summer of 1989 to allow the Glasgow Centre to perform an evaluation of this assay (SNB.001.9611). The results of this were communicated to Dr Harold Gunson in October 1989 (SNB.006.1596).

b) Following the launch of the Abbott first generation HCV assay in the summer of 1990, the Glasgow centre (along with North London and Newcastle) each performed approx 3500 tests on routine donor samples to ascertain the specificity of both the Abbott and Ortho first generation HCV assays.

c) The Hepatitis Reference Laboratory at Ruchill was heavily involved in performing HCV confirmation tests on the reactive samples from the National evaluation in b) above. This led to the realisation that suitable confirmatory tests had not yet been developed (PEN.017.1924; SNB.002.0279; SNB.005.4749; SNB.001.9032; SNB002.0294; SNF.001.1479).

SNBTS anticipated early introduction of HCV testing (Professor Cash's letter to SNBTS Regional Directors dated 27th November 1990 – SNB.005.2555) and took immediate action to prepare for this. Whilst SNBTS did not press for introduction of testing prior to the ACVSB decision in November 1990, understandably recognising and accepting the authority of the ACVSB, the evidence describes its very substantial contribution to the overall UK operational planning and test evaluations to ensure as rapid an introduction of testing as possible following the announcement of the government decision, based upon advice provided by the ACVSB.

Whilst the period up to November 1990 was dominated by considerations of the evolving science and international experience and by an apparent desire to apply high standards of scientific rigour to its decision making, the subsequent period up to routine introduction of the test in September 1991 appears to have been dominated by administrative, financial and managerial issues concerning implementation on a single uniform date. Further, the ACVSB committee gave advice not to proceed with first generation testing but to evaluate the much improved second generation tests when they became available. The action taken by one part of the UK (Newcastle) in its unilateral introduction of HCV testing in April 1990 (in response to the ACVSB recommendation to introduce testing 'as soon as practicable') was roundly condemned by UK colleagues and government officials. This episode served as a powerful disincentive for others to follow suit and further reinforced the principle of a uniform start date.

In addressing the question of why donor screening was not implemented until 1st September 1991, it is necessary to have regard to the situation in England and Wales. There was no direct evidence about this. The evidence about the situation there is largely inferred from documents (i.e. minutes of the ACVSB and ACTTD meetings and letters from Dr Gunson) and conjecture about administrative and, in

particular, funding problems. Professor Leikola has opined that the UK ought to have decided earlier to start screening blood donors (see statement PEN.017.1957 at 1959 and statement PEN.017.1961). However, he was never asked about and gave no evidence as to when Scotland, as distinct from the UK, could or should have started testing earlier than it did. Whilst Finland and Scotland are countries of a similar population size, they cannot be compared for the current purpose. Finland is an autonomous country in its own right, whereas Scotland is part of the UK.

For whatever reason the proposed start dates of 1st April and then 1st July slipped. Whether or not England and Wales could have started screening before 1st September (as opposed to whether they ought to have) is a matter of conjecture. It seems clear that in effect Scotland was in a position to start donor screening before 1st September 1991. (See Dr Perry statement PEN.017.2108 at 2118 and his evidence on day 68 pages 127/128 and 134-139; Dr McClelland at day 68 page 127 and 139 and at day 69 at page 63; see also Professor Cash at day 72 pages 157-175 and day 82 pages 14/15.) Given the structure then in place it would seem quite impracticable to consider any time before the decision of the ACVSB on 21st November 1990. The question that arises in relation to Scotland is whether Scotland could or should have considered introduction at a period after 21st November 1990 but before 1st September 1991. Here it is vital to appreciate the advantage we now have in 2012 in viewing events between 1989 and 1991 and to put any examination in the context of contemporary knowledge. We now know that donor screening was not introduced until 1st September 1991. That was not known in January or March or June 1991.

Whilst there were proponents of an earlier start, i.e. Dr McClelland, Dr Perry and Mr McIntosh, those individuals recognised that a simple "UDI" was not possible and that SHHD approval was necessary (see Dr Perry evidence day 68 page 128 and 139; Dr McClelland on day 69 at pages 63 and 88 and Mr McIntosh on day 70 at pages 118, 125 and 147. See also Professor Cash's letter to Dr Gunson of 28th July 1989 - "some points about the future (a) we will not move unilaterally unless instructed to do so by SHHD" (SNB.008.2606)). It was recognised at the time that the SNBTS alone could have done nothing other than seek to influence the SHHD - see Dr McClelland on day 69 at page 76/77 and Mr McIntosh on day 70 at pages 118 and 125. Notwithstanding the position adopted before this Inquiry by Mr McIntosh, it is clear that even those who favoured earlier introduction recognised the benefits in UK wide uniformity. Indeed, that was Mr McIntosh's view as at August 1991 (see exchange of correspondence between Mr McIntosh and Professor Cash - SNB.002.0457 and SNB.005.4822). Before this, the matter was considered by the Board of Directors of SNBTS at their meeting of 11th/12th June 1991. The outcome appears to be recorded in Professor Cash's letter of 12th August 1991 to Mr J Donald, General Manager, CSA (SNB.008.3956). At the meeting on 11th/12th June 1991 it was known that the proposed UK starting date of 1st April had gone by, that 1st July was not achievable and that 1st September was by then the suggested date. The majority view appears to have been not to make any approach to SHHD.

Ultimately, the questions which arise are (1) whether had any such approach been made by the SNBTS to the SHHD it would have been successful and (2) if so, whether this would in fact have resulted in the introduction of donor screening before 1st September 1991.

Notwithstanding Mr McIntosh's personal opinion that such an approach would "surely" have been successful (statement PEN.017.2126 paragraph 7.10 at 2140), the weight of evidence suggests otherwise. It would have been necessary for the SNBTS to provide a very robust and compelling argument for Scotland to introduce

donor screening in advance of the rest of the UK. Given that even proponents for an earlier start (i.e. Perry and McClelland) recognised the validity of competing arguments, it is difficult to envisage how a representation could have been made which would have had the necessary impact to persuade the SHHD to abandon the existing policy for a single UK wide start date. No doubt if it had been anticipated that England and Wales would not have been ready until, say, September 1992, then such an exercise would have been considered worthwhile and may well have met with success, but this is of course speculation. It is frankly difficult to see the mindset of SHHD officials or Ministers being altered however persuasively such a presentation had been made, particularly given their repeated and consistent assertion of a common UK start date and their (and presumably Scottish Ministers') acceptance of a DOH lead (see Forsyth – PEN.017.2799).. There are few, if any, precedents on which to judge the likely success or impact of divergent action by Scotland on a key public health topic such as this, but it is most likely that SHHD would have reasserted its support for a single UK wide start date – in line with its undertaking and commitment on the issue since 1988.

Whilst considering these matters, it requires to be kept in mind that the Glasgow centre, which handles more than 50% of Scotland's blood, actually started HCV screening (with second generation tests) approximately 3 months ahead of other Scottish (and most UK) centres (PEN.017.1923-4). The reason for this was that the Glasgow centre had just completed a successful evaluation of the Abbott second generation HCV test (SNB.006.4037 and SNB.011.8372) and was in a position (through funding from DOH) to continue the evaluation in a live situation, where all donations would be routinely screened and repeatedly reactive donations removed from blood at issue (SNB.005.1711). This also allowed for the SNBTS Microbiology Reference laboratory to be formed to provide a confirmatory service. In this period, excellent collaboration was established with Professor Peter Simmonds of University of Edinburgh and this led to the discovery and patenting of the HCV genotype 3. Other centres in Scotland also started testing ahead of time, to ensure that all blood donations in stock as at 1 September 1991 had been tested.

As Professor Leikola reminded us (statement PEN.017.1961 at 1963), the seriousness of the effects of transfusion transmitted Hepatitis C was not fully appreciated at that time, there being a perception that it seemed often very mild or totally asymptomatic. While in hindsight it would appear that Scotland could theoretically have introduced donor testing before the rest of the UK, the SNBTS had no means of influencing or altering UK policy. For Scotland to have started testing earlier would have required a radical departure from the orthodoxy of the then existing governance arrangements and the precedent set by the UK wide introduction of HIV testing.

In relation to Inquiry Counsel's Question 8, it is submitted that the decision of the Hon. Mr Justice Burton MA and others is of no relevance to this Inquiry. The claims in that litigation which were solely based on the Consumer Protection Act 1987 were successful on the basis of the judge's interpretation of Sections 3 and 4 of that Act (i.e. Articles 6 and 7 of the EEC Product Liability Directive 1985). Underlying the judge's construction of these provisions was a finding about the knowledge of the general public in relation to the likelihood/ possibility of infection from blood products. None of the six lead cases in A & Others were haemophilia patients, all six receiving blood in the course of operative procedures. The claimant's success in a litigation based on a single judge's interpretation of a strict liability legislation provision should not, it is submitted, influence this Inquiry whose remit is entirely different and is restricted to Scotland.

As a generality, the chairman of a statutory Inquiry of this sort should not in any way be fettered by the decision of a single judge sitting in the Queens Bench Division in England.

Topic B5b

PENROSE INQUIRY

TOPIC B5b

Evidence was given on this topic by:-
(1) Dr John Gillon (Day 38)

The relevant statement on this topic is:-
(1) Dr John Gillon PEN.012.0862

SNBTS briefing paper relevant to this topic is:-
(1) SNBTS briefing paper on Lookback – Procedures to identify, trace and offer counselling and testing to patients who received blood components found to be positive in tests for HIV and HCV PEN.017.2220

TOPIC B5b

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

Topic B5b – Inquiry Counsel Issue No: 7

7. The response on the part of SNBTS in the period 1985-90 to the introduction of testing for the HTLV III virus which allowed a targeted look-back of patients who had received blood components made from donations given by donors who had tested positive for the HTLV III virus

- In July 1985 a Working Party set up by the UK Regional Transfusion Directors to advise on the implementation of testing blood donors for antibody to HIV/HTLV III issued their report, entitled "Screening of blood donations for anti-HTLV III in Regional Blood Transfusion Centres" (1). Drawing on recommendations already accepted in the USA, the authors recommended that "Efforts will be made to determine the names of any patients who received blood or components from the donors (found to be positive) taken during the past five years and information given to the consultant in charge of the patient." In other words, the procedure which came to be known as "lookback" was to be carried out systematically as soon as testing began.

  This policy was adopted by the SNBTS and implemented after appropriate training had been provided for the doctors in the transfusion centres charged with this responsibility, with effect from October 1985. In addition to this "targeted lookback", which begins with identifying a donor as positive on testing for HIV, the SNBTS investigated all clinician reports of HIV possibly resulting from blood or blood component transfusion, which begins with identification of a recipient of a transfusion found to be positive for tests for HIV.

  These efforts resulted in the identification of 18 patients with HIV infection attributable to blood or blood component transfusion, 10 from targeted lookback and 8 from clinician reported investigations (2). The earliest known transmission was in August 1983, the latest in August 1986. This last transmission was a window period transmission. Window period is the interval between exposure to an infectious agent and the appearance of detectable antibody or antigen in laboratory tests on the blood; during which time the exposed individual's blood may be highly infectious, in spite of having negative results.

  Eight of these cases occurred in Lothian, 6 in Greater Glasgow, 3 in Tayside and 1 in Lanarkshire.

  The SNBTS, in common with the other UK Transfusion Services, acknowledged the seriousness of infection with HIV/HTLV III, and acted expeditiously and with all diligence to trace the affected patients in order to offer them the possibility of counselling, testing and further specialist medical care.

Lookback demonstrated that HIV entered the Scottish donor population in mid-1983. By the time that testing had been introduced in October 1985, the risk to patients had already been significantly reduced by increasingly stringent donor selection introduced from 1983 in response to increasing knowledge of the behaviours which put donors at risk of infection. The risk to patients was virtually eliminated when testing began in October 1985. Subsequent development in test methods and the introduction of testing for viral DNA has increased safety to the point where no window period transmission has been documented since 1986.

References

1. Report “Screening of blood for HTLV III in Regional Transfusion Centres”, 11 July 1985
2. Transcript of Dr Gillon’s evidence, March 16, and witness statement PEN.001.0038.

Topic C5b

PENROSE INQUIRY

TOPIC C5b

Evidence was given on this topic by:-
(1) Dr John Gillon (day 86, 18 January 2012)

The relevant statement on this topic is:-
(1) Dr John Gillon PEN.018.0410

SNBTS briefing paper relevant to this topic is:-
(1) SNBTS briefing paper on Lookback – Procedures to identify, trace and offer counselling and testing to patients who received blood components found to be positive in tests for HIV and HCV PEN.017.2220

TOPIC C5b
The tracing and testing of patients who might have been exposed to the virus through their treatment with blood or blood products

Topic C5b – Inquiry Counsel Issue No 6

6. The response on the part of SNBTS in the period 1991-95 to the introduction of testing for HCV which allowed a targeted look-back of patients who had received blood components made from donations given by donors who had tested positive for HCV.

- In 1989 the hepatitis C virus had been discovered and a test was in prospect. Initial estimates put the population prevalence in the USA and Northern Europe at 1-2% (1, 2). The early UK three Centre study using the first generation test suggested a prevalence in Scotland between 0.5 and 0.6% (3), and on this basis it was thought that the numbers of patients possibly infected by transfusion in the preceding years might be so great that tracing and offering testing to them in a targeted lookback might prove impossible. Therefore, most of the countries which commenced testing during 1990, using the first generation test, did not institute targeted lookback, with notable exceptions such as Holland (3).

  In June 1990 the SNBTS set up a small working party to advise on the management of donors found to be HCV positive when testing was introduced. This working party produced a draft report in September 1990, and in that report recommended the implementation of lookback as a routine procedure from the commencement of testing, while acknowledging the resource implications if the estimates of prevalence in donors proved to be accurate (5). This report was accepted by the SNBTS Directors and the SNBTS Medical and Scientific Committee (MSC), and it was shared with other UK Transfusion Services. However, discussions at the ACVSB and ACTTD led to the recommendation on lookback being rejected, a decision which was then endorsed by the MSC and communicated internally by letter in February 1991 (6).

  By this time in 1991 studies had begun with the second generation test and prototype confirmatory tests were also becoming available. It was becoming clear that the numbers affected were much less than initially feared (almost 10 fold less) (3), suggesting that the logistical difficulties with lookback may have been overestimated. In the Edinburgh and South East Scotland Transfusion Centre (SERTC) HCV lookback was carried out from the introduction of testing in September 1991. This work was regarded as a pilot study, and the results were published in December 1994 (7). The main finding was that lookback was logistically feasible and welcomed by patients, and this led to reconsideration at UK level of the lookback policy.

  In April 1995 the CMO issued guidance that HCV lookback was to be carried out in the UK, and efforts made to identify all surviving patients traceable as a result of donor testing (8). Formal procedures and documentation were produced, and from April 1995 the lookback was implemented across the UK, making it one of the first major Western countries to do so.

In Scotland, as in the rest of the UK, the lookback proceeded rather slowly, illustrating the practical difficulties in tracing patients transfused many years earlier, but in 1998 the SHHD confirmed that SNBTS had done everything within reason to trace patients, and that the retrospective exercise could be regarded as complete (9). 133 patients had been found to be alive and positive for HCV, and they were then in a position to be referred for specialist medical care and consideration of treatment. In addition to the 133 patients identified by targeted lookback, others were identified after presenting with hepatitis C to clinicians who then reported the possibility of transfusion transmission to SNBTS. The overall total number known to be alive and carrying HCV at the end of the lookback or after SNBTS investigation was 217. The earliest transmission accepted as definite was in 1977, and the last in March 1991. SNBTS is not aware of any transmission occurring since the introduction of HCV testing in September 1991.

The region in which transfusion transmission occurred is known for a subset of 103 patients. 42 were in Greater Glasgow/WBTS, 24 in Lothian, 21 in Tayside, 10 in Aberdeen and 6 in Inverness.

The SNBTS was highly proactive in attempting to persuade the UK Transfusion Services to adopt HCV lookback from the commencement of testing, and that, this initiative having failed, SNBTS medical staff carried out work which played a critical part in persuading the relevant UKBTS and UK Government Advisory Committees to implement a policy which was seen to be ethically sound, feasible in both logistical and economic terms, and, most importantly, was welcomed by patients and their families.

References

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