

**Issue 6:**

**The information given about the risk of NANB Hepatitis (i) to patients or their parents before treatment with blood or blood products; (ii) to patients who might have been infected or who were found to be infected and in particular the apparent discrepancy between what a number of patients now recall and the evidence of Haemophilia Clinicians as to their practice at the material time**

**Topics covered:**

- 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;
- C5c) – The information given to patients who might have been infected, or who were found to be infected, and their families

# Topic C5

## PENROSE INQUIRY

### TOPIC C5

Evidence was given on this topic by:-

- (1) Professor Gordon Lowe (Day 80);
- (2) Dr Philip Cachia (Day 83);
- (3) Dr Charles Hay (Day 83);
- (4) Dr Vivienne Nathanson (Day 84);
- (5) Mr David McIntosh (Day 84);
- (6) Professor John Cash (Day 85);
- (7) Dr Graeme Alexander (Day 85);
- (8) Dr Aileen Keel (Day 86) and
- (9) Mr David Watters (Day 87).

As part of the evidence about the effects of infection with Hepatitis C, the question of information given to patients was mentioned by "Stephen" (Day 75); "Bridie" (Day 76); "Colin" and "Gordon" (both Day 77) and "Laura" and "Anne" (both Day 79).

The relevant statements on this topic are:-

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|------|---|---|
| (1)  | Collective response on behalf of past and present Haemophilia staff | PEN.018.0649                                |
| (2)  | Dr Vivienne Nathanson   | PEN.018.0419                                |
| (3)  | Dr Charles Hay  | PEN.018.1349, PEN.018.1179 and PEN.018.1186 |
| (4)  | Professor Christopher Ludlam  | PEN.018.0832 and PEN.018.1246               |
| (5)  | Professor Gordon Lowe   | PEN.018.0839 and PEN.018.1240               |
| (6)  | Professor Philip Cachia   | PEN.018.0853                                |
| (7)  | Dr Brenda Gibson  | PEN.018.0824 and PEN.018.1245               |
| (8)  | Dr Graeme Alexander   | PEN.018.1360                                |
| (9)  | Dr A J Morris   | PEN.018.0874                                |
| (10) | Margaret Neilson  | PEN.018.0885                                |
| (11) | Professor John Cash   | PEN.018.0353                                |
| (12) | Mr David McIntosh   | PEN.018.0358                                |
| (13) | Dr Aileen Keel  | PEN.018.0396                                |
| (14) | Sir Kenneth Calman  | PEN.018.0404                                |
| (15) | Dr Andrew Young   | PEN.018.0401                                |
| (16) | Mr George Tucker  | PEN.018.0406                                |

SNBB briefing papers relevant to this topic are:-

- |     |   |              |
|-----|---|--------------|
| (1) | SNBTS briefing paper on Hepatitis Risk Warnings   | PEN.012.0286 |
| (2) | SNBTS briefing paper on Lookback  | PEN.017.2220 |
| (3) | SNBTS paper – Events Concerning the Safety of Blood and Blood Products with Special Reference to the Treatment of Haemophilia | PEN.013.0220 |

**TOPIC C5**

**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;**

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

**C5c) the information given to patients who might have been infected, or who were found to be infected, and their families.**

**Inquiry Counsel Issues Nos: 1-5**

- 1. The steps taken by SNBTS to warn patients of the possible transmission of NANB hepatitis and Hepatitis C virus by their blood products.**
  - 2. The steps taken by haemophilia clinicians in Scotland to warn patients of the possible transmission of NANB hepatitis and Hepatitis C virus by blood products.**
  - 3. The testing of blood samples, including stored samples, from patients with haemophilia for the HCV virus in 1989 - 92**
  - 4. The response on the part of haemophilia clinicians to the results of tests showing that some of their patients had tested positive for the HCV virus.**
  - 5. The way in which information about infection with the HCV virus and prognosis was communicated by haemophilia clinicians and hepatologists to patients in the period 1989-95**
- The steps taken by SNBTS to warn patients of the possible transmission of NANB hepatitis and Hepatitis C virus by their blood products.

Evidence from Dr Perry in the form of witness statements PEN.018.0543 & PEN.018.0556, has been presented to the Inquiry in response to specific questions posed by patients' solicitors and Counsel to the Inquiry.

This evidence, which has been neither disputed nor challenged, describes the responsibilities and constraints of SNBTS as a manufacturer of pharmaceutical products concerning the provision of product information and warnings. Accordingly SNBTS did not and could not engage in any direct patient communication concerning infectivity or other risks associated with the use of its products.

SNBTS has provided evidence during the course of the Inquiry, PEN.018.0543 & PEN.018.0556, of hepatitis warnings on its labelling and product insert leaflets for products supplied. Evidence has also been provided that the warnings provided were approved by regulatory agencies, compliant with pharmacopoeial standards and comparable to similar warnings provided with contemporaneous commercial products.

These formal warning statements were intended for health care professionals but would also be available to patients, particularly those on home treatment.

Notwithstanding the regulatory requirement to provide such warnings with these products, it is unlikely that the formal warning statements provided by SNBTS added any information to the body of knowledge in the public domain and already widely understood by haemophilia doctors.

No evidence has been presented of error or omission concerning the risks of NANBH and Hepatitis C in the formal information supplied with its products or any other information or warnings.

- The steps taken by Haemophilia Clinicians in Scotland to warn patients of the possible transmission of NANB Hepatitis and Hepatitis C virus by blood products

The only Scottish Haemophilia Director to give evidence on this topic was Professor Lowe on day 80. He provided a statement PEN.018.0839 and made reference to a collective response statement PEN.018.0839. Reservations were expressed about the usefulness of the collective statement (Chairman, page 12) and privately Mr Di Rollo asked about the involvement of Billie Reynolds in the exercise. For that reason there accompanies these submissions a document entitled "Methodology of the Collective Response on behalf of past and present Haemophilia Centre staff in Scotland on Topic C5" that has been prepared by The Central Legal Office. This document seeks to explain how and why the document was prepared and it is hoped will firmly dispel any doubts about its reliability as evidence. Professor Ludlam offered to give oral evidence on this topic but that offer was not taken up by Inquiry Counsel.

It will be recalled that Professor Lowe agreed that his statement represented his own recollection of events (page 10). Haemophilia clinicians can only speak to their own practice and shared practice among all Haemophilia clinicians: see collective response PEN.018.0649 at page 5 i.e. 0653. Haemophilia clinicians had previous experience of Hepatitis A and Hepatitis B and patients had an awareness of the risks of hepatitis. Professor Lowe refers to guidance received from UKHCDO in his statement at 0841-0845 and this whole topic was fully explored in evidence on day 80 at pages 17-27, 31-37, 41/42 "I cannot recall a single patient that I saw for the first time who hadn't been told about Hepatitis" and page 45.

Professor Ludlam provided a statement of his own PEN.018.0832 and this question is dealt with at paragraph 2 in which he describes their policy of telling all patients/parents about the risks of haemophilia and its treatment, including the risk of hepatitis. Information sheets and booklets were given to patients to reinforce the message. There is also evidence of hepatitis being discussed with patients in Scotland in 1980. (See SNBTS Briefing Paper (page 9, para 4 and Ref 12, page 45) PEN.013.0220.)

- The testing of blood samples, including stored blood samples, from patients with Haemophilia for the Hep C virus in 1989-1992

- The response on the part of Haemophilia clinicians to the results of tests showing that some of their patients had tested positive for the Hep C virus and
- The way in which information about infection with the Hep C virus and prognosis was communicated by Haemophilia clinicians and Hepatologists to patients in the period 1989-1995.

The question of testing was referred to by Professor Lowe in his statement PEN.018.0845 at pages 7-14 and explored with him in evidence on day 80 pages 52, 54-5, 58-72 and 75-81. Professor Lowe was also asked to comment upon Dr Nathanson's supplementary statement PEN.018.0419 on the question of pre test counselling as (in writing) were Professor Ludlam PEN.018.1246, Dr Brenda Gibson PEN.018.1245, Dr Charles Hay PEN.018.1179 and Professor Philip Cachia PEN.018.1239.

The apparent difference between Dr Nathanson's report and Dr Hay's report appeared to evaporate by the time both had concluded their evidence. Dr Hay's own practice in relation to the information to be given to patients prior to testing is set out in his revised statement PEN.018.1186 at pages 27/8 paragraphs 63-68 and in evidence on day 83. The practice of the Scottish Haemophilia Directors was in accordance with the practice of Dr Hay and thus also has the approval of Dr Nathanson.

Dr Hay reminded the Inquiry that in relation to pre test "counselling" there was a range of practice (day 83 page 127) and (at page 128) made reference to Professor Bloom's view that the new Hep C test was just another liver function test - see minutes of AIDS Group of Haemophilia Directors meeting, 12<sup>th</sup> February 1990, page 4 - LOT.003.4450.

The use of the word "counselling" was a matter focussed upon at the close of Dr Nathanson's evidence on day 84 from pages 37-51 and pages 65-68. See in particular at page 38:- "Question: Dr Hay's position is that his practice was ... to advise his patients that he wanted to test them for Hepatitis, give them an exposition of the disease, effectively secure their agreement to the test. Would you take issue with that approach? Answer: That is, as far as I am concerned, pre-test counselling. Question: Would that accord with best practice for the period? Answer: Absolutely, yes." The problem with the use of the word "counselling" is perhaps best illustrated in the passage at day 80, page 76 where Professor Lowe is asked "Question: Was that the basis on which you decided that pre- test counselling was not required? Answer: Well, we gave pre-test information about the test" which is precisely what Dr Nathanson and Dr Hay describe as constituting pre-test "counselling".

Dr Graeme Alexander dealt briefly with the question of communication of results in his statement PEN.018.1360 at pages 6-7 and enlarged upon information given to patients at day 85, page 139 and pages 141-143.

In Chapter 4 of the Preliminary Report it is recorded at 4.35 that "the great majority" of witnesses (i.e. 17 out of 23, 22 being haemophiliacs) told the Inquiry that they were not warned about risks associated with the

treatment that they were receiving. At 4.51 it is recorded that “a theme that emerged from speaking with witnesses was their recollection that they did not know they were being tested for Hep C and/or HIV”.

These statements have not been made available and their reliability cannot therefore be tested in any way. It is submitted that some of the misconceptions readily apparent in the evidence of the anonymised witnesses in both the B6 and C6 topics may assist in an understanding of how the recollections recorded in the Preliminary Report may be reconciled with the recollections of the clinicians whose evidence was the subject of careful scrutiny during the course of the oral hearings. In relation to the evidence of those anonymised witnesses, it was agreed that a conventional cross examination would not be appropriate, and on the basis that the purpose of hearing evidence from those individuals was to give a general impression as to the realities of living with the infection, rather than a fact finding exercise, no challenge was made. That, it will be appreciated, does not mean to say that their evidence should therefore be accepted as wholly reliable. In so saying, it need hardly be said that no question arises as to the essential probity of any of those individuals. As regards the discrepancy, Professor Lowe sought to explain this - see day 80, pages 111-114. He indicated in particular that he believes that clinicians made every effort to keep patients informed, and that patients and staff were on a “learning curve” when it came to Hepatitis C. It was a long journey which occurred a long time ago, accounting for some of the discrepancies in memory. Prof Lowe and others operated an open communication policy where patients were free to communicate with clinicians, and doctors did their utmost to provide as much information as possible to patients.