THE PENROSE INQUIRY

C5b – TRACING AND TESTING OF PATIENTS

1. What was Dr Young's involvement in the look-back exercise?

I was appointed DCMO in 1989 and covered Public Health responsibilities and Hospital Services and Medical Staffing. My first involvement with SNBTS was as a member of the CSA Management Committee.

I was periodically involved in consideration of an HCV look-back exercise by virtue of my dual post as Deputy CMO/Medical Director SHHD Management Executive.
1990. Dr McIntyre and, after 1992, Dr Keel had the Department's medical lead for Blood Transfusion and related services. They briefed CMO and me at least once a week at our regular meeting with medical staff, and more often if required. The main issue then was HCV testing and look-back.
At its meeting on 23 May 1990 the CSA Management Committee expressed concern about legal liability issues for CSA should HCV testing of blood donations be implemented or delayed and asked for a position paper for their June meeting. I briefed them on the situation namely that there was as yet no sensitive confirmatory test, false positive tests were a problem and there was no effective treatment. I wrote the memo dated 23 May 1990 to alert Dr McIntyre and Mr Tucker (Assistant Secretary) to the request for a paper. I do not recall such a paper being produced. I can only assume that things were changing so rapidly that oral updates were given.

1991. I was not directly involved in the work up to the introduction of screening donors for HCV and subsequently the introduction of look-back. I was part of the system generating the Scottish version of CMO letters to all doctors including CMO 95/1 and 95/7 but this was more of a proof reading function.

2. Anti-HCV testing commenced in Scotland in September 1991. Why was a look-back exercise not commenced at that time? Cf. HIV look-back which began at the same time as HIV screening in October 1985.

The reasons why the lookback exercise was not launched at the same time as the anti-HCV testing was because there were gaps in the scientific and medical knowledge; for example the natural history of the disease was not fully known.; there was no cure available; and no feasibility study had been completed.

3. On 3 April 1995, comprehensive guidance on anti-HCV testing and HCV generally was issued to all doctors in Scotland in the form of a CMO letter.

However, anti-HCV testing had been introduced more than three years earlier in September 1991 and diagnostic testing had been available since 1990. What steps, if any, did the SHHD take to draw doctors' attention to the availability of testing and implications of HCV for patients before April 1995?

CMO letter 95/1 on 11 January was timed to coincide with a reply to a written PQ. I don't know of any prior notification to doctors in general but SNBTS staff were involved, as were some haematologists, in advisory bodies and knew the state of affairs.

4. In early 1995, the ad hoc Working Party agreed that the look-back exercise should be concentrated upon donors who had given blood prior to September 1991 and been found to be Hepatitis C antibody positive after the introduction of testing in September 1991. The WP decided that the blood transfusion services would not try and trace donors who had not come back to a Transfusion Centre since then.

   Were any efforts made in Scotland to contact people who received blood or blood products prior to 1991 where the donor had not returned to a Transfusion Centre? If not, why not?

   Were any steps taken to publicise the risk that individuals might have contracted HCV from blood and blood products administered before September 1991? Was the availability of testing publicised to the general public (and more particularly, recipients of blood or blood products who may have been exposed to HCV prior to 1991)? If so, what arrangements were made for any such individuals who wished to be tested? If not, why not?

My understanding of the decision to concentrate on post 1991 donors and recipients was that donors were a known set who were alive and in touch with the service and recipients' hospital records were likely to be available A pilot study had confirmed feasibility. Tracing all pre 1991 recipients could prove difficult but some might read about the look-back in the press. Anyone in that category who sought advice from their doctor or the SNBTS would of course be counselled and, if they wished, tested.

5. The ad hoc Working Party also advised that the look-back should not be extended to other blood products. What products were included within the HCV look-back? Why was the look-back not extended to all blood and blood products?

The look-back included fresh frozen plasma, red cells, platelets and cryoprecipitate. Plasma that went for fractionation would not need to be traced back. But I do not remember when viral inactivation procedures were introduced for IVIG or factor 8.

Statement of Truth

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

Signed ... GRO-C

Dated 9-11-11