

**THE PENROSE INQUIRY
STATEMENT OF DR ARCHIBALD D MCINTYRE
C2 – SUPPLEMENTARY**

The summary in paper A38242 and the Chronology detailed in A37756 demonstrate the problem of reaching a logical rational decision on whether or not to introduce a screening test for a clinical condition of unknown aetiology (other than that it developed in some people following receiving blood or blood products); using a surrogate test based on a test used for a similar condition plus a liver test which is non specific.

(1) Should a large scale prospective study, as originally proposed by Dr McClelland in 1981 (i.e. along the lines of the US TTV and NIH studies and including the follow-up of recipients), have been carried out in the UK in the early 1980s (or at some point thereafter) with the following aims:

- (a) to assess the prevalence of post transfusion NANBH in the UK,
- (b) to evaluate surrogate markers for the disease.
- (c) to investigate the natural progression and seriousness of the disease, and
- (d) to produce a library of "known" infected sera with which to evaluate any future assays which became available?

1. The first paragraph of the summary indicates that the study did not receive support from the MRC Working Party. This is a body well able to advise on such research. Even after years of discussion the SNBTS Directors wrote to the Lancet saying that surrogate testing was "irrational, perhaps, but inescapable". The answers to the various questions are really a matter for those working in the clinical aspects of the service.

(2) If such a study had been carried out, to what extent is it likely to have met the objectives set out in (1) above? To what extent would such a study have provided more information upon which to base a decision on whether surrogate testing should be introduced?

2. The words "if" and "is it likely" make this a hypothetical question for which I cannot hazard an answer 25 years later.

(3) Did the conclusions of Drs Dow and Follett place sufficient emphasis on the likely prevalence and seriousness of post-transfusion NANBH? In particular, as well as having regard to reported cases of the disease, did the work of Drs Dow and Follett have sufficient regard to the fact that most cases of NANBH were sub-clinical and were unlikely to be detected without prospective follow-up (by biochemical testing) of recipients?

3. Dr Dow and his colleagues would be well aware from the literature, personal contacts and their own researches of the situation. As outlined in the introductions to chapters 7 and 9 it became clearer as the 1980s progressed that Non A, Non B could be a more serious condition than originally thought.

(4) In the second half of the 1980s, did SHHD medical officers place sufficient weight on the likely prevalence and seriousness of post-transfusion NANBH.¹ To what extent did their views in that regard influence their opinion on whether surrogate testing of blood donors should be introduced?

4. By attendance at relevant committee meetings and from the literature SHHD medical officers kept up to date on developments and were able to present to their admin colleagues the pros and cons of surrogate testing. My minute of 6 April 1987 (SGH.002.8127) is an example. Dr Forrester's minutes referred to at paragraphs 9.38 (SGH.002.8137) and 9.43 (SGF.0012102) and the obtaining of Dr Dan Reid's opinion referred to in paragraph 9.28 reflect the serious way in which this matter was regarded.

(5) If surrogate testing of blood donors (i.e. testing for elevated ALT and/or anti-HBC) had been introduced in Scotland:

- (a) what percentage of donors are likely to have been deferred,
- (b) could a sufficient blood supply have been maintained, and
- (c) to what extent are cases of post-transfusion hepatitis C likely to have been prevented (having regard, for example, to the finding that in the first six months of HCV screening the prevalence of HCV in Scottish blood donors was 0.088%, and that elevated ALT levels were found in 59% of HCV positive donors)?

5. Clinical colleagues may be able to provide specific answers to these questions as I do not have sufficiently detailed knowledge of the issues on which to base a response.

Statement of Truth

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

Signed And: D. McInyre.....Dated 29-9-11.....