THE PENROSE INQUIRY

WITNESS STATEMENT – DR RUTHVEN MITCHELL

TOPIC NUMBER B4

I confirm that the snapshots and landmarks noted are in my view essentially correct.

SNBTS EVALUATIONS

In a letter to Dr A E Bell dated 24 January 1985 [SNB.005.7304], Dr Cash noted:

> **"The biggest anxiety of the NBTS Directors with regard to this problem is the Scots: that they will unilaterally move to come in line with American proposals. They're right: we are in detailed discussion with commercial (kit) companies, our technical staff are already looking at ways of introducing the technology within existing staff establishments, we have the Western Blot technique (HQ and SE Labs), we are already liaising with local (Communicable Disease) physicians with a view to securing care for our positive donors and we are currently arranging our financial planning accordingly..."**

On 25 January 1985, Dr Cash wrote to Dr Mitchell [SNB.005.9713]. Dr Cash advised that WBTS should undertake, on behalf of the SNBTS, initial evaluation studies of commercial HTLV-III antibody kits.

At the SNBTS Co-ordinating Group meeting on 19 February 1985 [SNB.003.9171] it was decided that Dr Cash's letter should not be pursued at the present time.

What particular steps had the SNBTS taken with regard to the introduction of HTLV-III screening in Scotland as at 24 January 1985?

Major steps were being taken by the SNBTS well before January 1985. Professor Cash's letter to Dr Bell [SNB.005.7304] confirms that many of us were aware of Abbott Laboratories developing a test in the USA from the isolate prepared by Dr Gallo. I was aware of the refusal of Dr Gallo to agree that the DHSS would have access to his isolate for protection of the P24 marker and the subsequent efforts of Dr Robin Weiss and Dr Richard Tedder in securing a British isolate to develop the Wellcome test.

What particular steps did Dr Mitchell take between 25 January and 19 February 1985?

When the SNBTS was considering its own evaluation, would this have occurred at the same time as the introduction of a commercial test or would a test have been introduced only after the evaluation had been completed?

Did the SNBTS abandon its own evaluations altogether and await the DHSS evaluations and, if so, why? Was the decision to await the results of the DHSS evaluations made by the SNBTS or the SHHD? What discussions took place between the SNBTS and SHHD regarding this matter?

In asking Glasgow to undertake an evaluation of any available or any semi-commercial kits Dr Cash and everyone else was aware of the difficulties of obtaining the kits from Abbott Laboratories and Organon Laboratories. Dr Peutherer in Edinburgh and Dr Follett in Glasgow intended to have confirmatory testing techniques available but when Professor Cash asked Harold Gunson to release some of the English test materials from Wellcome it became clear that the DHSS had commissioned at their own expense an English RTC evaluation which had resulted in an unacceptably high number of false positive reactions confirmed by their virology reference laboratories.

The English were naturally reluctant to release any "free" reagents to Scotland although we had a high reputation in handling commercial kits. We had great difficulty in obtaining kits from the USA and elsewhere and only received a small batch to familiarise ourselves with the technology and to have some hands-on experience. (I cannot recall when these materials were received but suggest that Dr Brian Dow may have this information.) These test materials could not be subjected to the wide range of scrutiny that we would otherwise have given.

I believe it was around May or June 1985 that Dr Mortimer and others were able to report their findings in the DHSS evaluation. I am not sure how far Dr Cash reinforced his requests for trial reagents. Information on the DHSS evaluation of the Wellcome and Organon kits is well described by Dr McClelland in his account in paragraphs 3.3, 3.4, 3.5 of the document entitled "Actions taken by the SNBTS to protect patients from AIDS" [SNB.014.3070] and Dr McClelland also describes the involvement of Dr Robin Weiss, Dr Tedder and Dr Mortimer with the Wellcome laboratories.

I have asked Dr Dow if he can recall any other information and he recalls that version 1 of the Wellcome test kit, of which he received a small test supply in July 1985, was pronounced very good but later when the test was introduced it had considerable difficulties in the reading and was subject to technical failure such that many tests had to be repeated and a pre-incubation step

introduced into the testing procedure to provide readable results within a reasonable timescale of one day. Meetings were held by Wellcome and Wellcome user group meetings were held with all UK centres acting in unison from 15 October and also testing any stocks for blood and blood products in reserve up to 1 month earlier by which time all centres were up to speed and only Sheffield was performing the Organon test. Any fear on the part of the NBTS that Scotland might "go it alone" were dispelled.

INTRODUCTION OF HTLV-III SCREENING IN SCOTLAND

The minutes of the SNBTS Directors meeting on 2 October 1985 [SGH.001.6412] record that the East, South East, North and North East regions had all chosen the Wellcome test by that date.

Which test was chosen for the West?

For reasons already stated, the West and other Scottish regions introduced the Wellcome test.

The minutes also note that the South East and North regions had only purchased a 3 month supply.

With this in mind, could a short term supply contract have been entered into at an earlier date (ie. whilst the first stage of the evaluation was being undertaken)?

The fact that some centres ordered variable amounts of the reagent reflected their own financial position toward the end of the financial year but each regional transfusion centre may have had other ideas on which I am unable to comment. Dr Cash or the CSA would know what funds had been allocated for the introduction of the Wellcome tests.

In my view it would have been unwise to introduce an interim unvalidated test whilst validation was being carried out. As always, it is important to have a steady flow of reliable results and not take up additional resources or manpower in the testing laboratory or in the reference laboratory.
The question of a short term universal contract during the evolution and deliberations on the testing evaluations would be difficult to sustain because a) no decision had been made to override any evaluation and b) funding for such a venture would not have been agreed for any one region so as to avoid premature regional variation within donor and patient anxiety.

Consideration given to the idea of introducing commercial tests as an interim measure

On 21 February 1985, Dr Mitchell and others from the SNBTS and NBTS sent a letter to The Lancet [SNF.001.3361]. The letter stated "we the undersigned believe that the likely incidence of false positive HTLV-III antibody tests using the current generation of commercial kits in our voluntary blood donor populations will be high".

By comparison, Professor Bloom was anxious that one of the FDA licensed kits should be introduced immediately and wrote to the DHSS on 31 May 1985 to convey that view [DHF.002.5510]. With others (Charles Rizza and Charles Forbes), he wrote to the BMJ to similar effect, his letter being published on 22 June 1985 [LIT.001.0333].

It appears that the SNBTS/NBTS were concerned that the effect on donors would lead to a sizeable drop in the supply of blood and blood products.

What was the SNBTS/NBTS "belief" that the current generation of commercial tests were likely to give a high rate of false positive results based on? What was considered a "high rate"?

What, if anything, did the SNBTS/NBTS do to attempt to obtain information from larger blood transfusion services abroad in relation to the operation of the commercial tests?

What consideration, if any, did the SNBTS/NBTS give to how the effect on donors/transfusion recipients could be lessened, for example, by introducing testing without any public announcement or by deferring the giving of positive test results until the results had been confirmed by a reliable test method?

In a letter dated 8 January 1985 from Dr McClelland to Mr Madden (Wellcome Foundation) [SNB.005.9501], Dr McClelland states:

> **"I would emphasise that in my own centre at least, we would be very prepared to use, in the interim, some form of test procedure which might be considered less than satisfactory for a large scale, long term screening programme".**

What was envisaged here? Was any consideration given to the idea of introducing the Wellcome test at Dr Mitchell's centre as an interim measure? Was any consideration given

to the idea of introducing one of the US commercial tests as an interim measure at Dr Mitchell's centre or more widely throughout the SNBTS?

The letter from all of the UK RTD's [SNF.001.3361] was self explanatory because it was clear that commercial kits used in the USA were of variable quality and variable false positivity. There was no guarantee of confirmatory testing of so-called "walking well" or "walking wounded" donors. Samples tested by Professor Bloom and Dr Forbes and other Haemophilia Directors were of course based on small groups of patients who had received quantities of American concentrate. Equally there would be a considerable difference between non-remunerated UK donors and remunerated high risk donors in the USA giving by plasmapheresis in the plasma processing facilities. Introducing tests "by the back door" would result in a public deluge of condemnation verging on public loss of confidence in the BTS and accusations of malpractice and unethical conduct.

As has been stated frequently in other evidence to the Inquiry the Blood Transfusion Service was anxious to avoid cross regional visits by bogus donors looking for a free test and that is the reason that the Lancet letter suggested that testing should not be introduced until such times as Health Boards had reliable testing facilities elsewhere than in the transfusion centres.

I do hope that these comments are helpful to the Inquiry. Perhaps Dr Dow could give more information concerning the papers on the false positive date for various tests reported by Dr Mortimer and reviewed by Dr Gunson and Dr Rowlinson. Unfortunately I do not have access to these papers.

Ruthven Mitchell
31/08/11