NQJ/418

Copy to NQH/231
NQH/233

From: **G W Tucker**
NHS ME - PSDD
5 October 1994

Dr Keel
Mr Panton

Copy to: DCMO

ADVISORY COMMITTEE ON THE MICROBIOLOGY SAFETY OF BLOOD AND TISSUES FOR TRANSPLANTATION

As you know I attended the meeting of the above Committee on 29 September because of the unavailability of any representative from MED Group and the need to ensure that the Scottish Office views on ALT testing and HCV look-back were not sidelined. You will wish to know that Dr Perry did not attend the meeting and that there was only Dr Mitchell to represent a Scottish viewpoint. Dr Perry did write to the Committee opposing the introduction of ALT testing and a copy of his letter is attached.
* NQH/233

I found the meeting a most interesting one even although some of the technicalities were beyond me and on reflection I would like to think that my attendance was useful and worthwhile in making DofH and the NBA aware of where the Department stands at present on these 2 specific issues.

There will be an official note of the meeting but for your information, I noted the following points/decisions in the order taken on the agenda:-

(a) **Combined HIV and HTLV Test**

This was deferred for further consideration as there is a further meeting in October of a working group.

(b) **Transmission of Yersinia by Blood**

There is a gap in the current reporting arrangements. It was remitted to Dr Mitchell and Dr Robinson to come back with further report for the December Meeting of the Committee.

(c) **Dura Mater**

There had been a meeting with DofH Ministers who are content to endorse the line and advice given by the Committee on this.

(d) **Tissue Banks**

There are 30 such banks in the UK but no central source of information. The Scottish Banks have common operating procedures and standards with regular meetings but other parts of the UK are not so good.

There is a feeling that some form of central registration may be required. A draft report will be circulated to Health Departments by end of November.

The question was asked whether this Committee was the appropriate one to consider ethical and other issues relating to tissue use but it was indicated that there would seem to be no other appropriate alternative Committee.

(e) **HIV O**

The risk in this country is considered to be very small and therefore not sufficient to justify a change in the present arrangements. If Committee wish to offer that view the DofH Minister will be content.

(f) **HVC Look-back**

Dr Robinson explained that there now appears to be a means to treat some patients and it is felt Blood Transfusion Service has a a duty of care. Patients should be traced and counselled although it was recognised that this could have a serious impact on hepatolgists. It is estimated that there are 3,000 cases in England and Wales. David McIntosh's paper was quoted in support of the look-back. However Professor Zuckerman thought the figures in the English paper had been grossly exaggerated and he made the following points.

1. Trials in Belgium had shown that the figure of treatable patients was more likely to be 20% and not 60% (25% of carefully selected young patients and perhaps up to 40% under the very best conditions).

2. Interferon was expensive form of treatment, had nasty side effects and was not licensed for HCV.

3. The vast majority who have acquired the infection would not respond. It seems likely that a look-back would lead to demands to start screening everyone for HCV and there would be problems of litigation.

While there was some support for a look-back for children there were doubts expressed about the reliability of hospital records. I am not sure that this applies in Scotland but I expressed the view that we had reservations about a look-back unless it was on a UK basis and there were real benefits for patients in treatment. It was agreed that further work needed to be done looking at the legal and ethical dimensions. It was remitted to be brought back at the next meeting. In the meantime it would be necessary to assess cost implications and do a cost benefit analysis. Mr McMaster is to write with some further comments. A sub group of Dr Robinson, Dr Cant and Professor Zuckerman would consider all the comments made on Dr Robinson's paper and bring back a further paper. DofH will look at costs and legal obligations. The matter to be discussed again in December.

(g) **Safety of Transplantation of Human Tissues**

There is a need to inform DofH Ministers about the guideline document and to take the views of the lawyers on the content before issuing it for consultation.

(h) **ALT Testing**

Dr Robinson spoke to her paper and confirmed that the motive was to generate income from Europe otherwise the surplus would have to be destroyed. It was acknowledged that there was no patient benefit. I explained that we would find it difficult to recommend it to our Ministers and it could be damaging to donor base since the test was being introduced for a commercial reason. The other territorial Departments were also concerned and reminded DofH that if testing was to be introduced it should be on an agreed basis for the whole of the UK. It seems that Germany and France will not be persuaded that there is now no scientific basis for the test.

Dr Metters summed up by saying that it was not possible to say an absolute no to the proposals as there were other considerations. There was a need therefore to go to Ministers on this.

After the meeting DofH showed me a copy of a letter from Professor Cash which seems to support the introduction of ALT testing but I indicated that he was at odds with Dr Perry and our view.

(i) **Quarantining of FFP for Clinical Use**

There was agreement in principle to Dr Robinson's paper.

If I have misunderstood any points and if you consider that I have been rather expansive with these comments then I apologise. I hope however these are of interest. We await the further consideration and deliberations by the Committee.

G W TUCKER
NHS Management Executive
Head of Provider Strategic Development Division
Room 260
SAH
Ext 2269
5 October 1994