0046

IN CONFIDENCE

SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE

Minutes of an additional Co-ordinating Group
Meeting held in the HQ Unit on 30 April 1986

Present: Dr D B L McClelland (in the chair)
Dr E Brookes
Dr R Mitchell
Dr R J Perry
Miss M Corrie (Secretary)

1. INTRODUCTION AND APOLOGIES FOR ABSENCE

Dr Jack Gillon, Edinburgh Transfusion Centre attended for item 2 and Drs E A C Follett and John S Peutherer for item 4.

Apologies were received from Dr Cash, Mr Francis, Dr Morris McClelland, Dr Urbaniak and Dr Whitrow.

2. DONOR SELECTION CRITERIA
Deferred from Co-ordinating Group 25 February

Dr Gillon introduced his paper of 11 November 1985 which had been circulated previously. He recognised that he had misunderstood some matters when visiting Transfusion Centres and Directors had written to him to correct these. Dr Gillon had recommended in his report that the NBTS guidelines should not be adopted by the SNBTS in their present form and that a comprehensive set of selection criteria should be prepared in draft form for discussion. Those present agreed that there was a need for an SNBTS set of criteria to serve as a framework for use by medical officers and other team staff. It was agreed that it was for each Centre to decide who should take clinical decisions on donor acceptance. *

Dr Gillon tabled a draft alphabetical guide to medical acceptance which is used in the Edinburgh Centre. The Directors present agreed to recommend to the full Co-ordinating Group that a standard guide should be produced and that the Edinburgh document provided a basis for this, and could be amended in discussion with the Directors. Miss Corrie undertook to send a copy to each Director who had not been present and everyone was asked to send comments to Dr Gillon. *

Specific points in the alphabetical guide were discussed as follows:-
Dental treatment: it was agreed that the Edinburgh recommendation ('defer for 72 hours if extractions. Otherwise may donate') should read "at least 72 hours".

Electrolysis: it was agreed to accept the Edinburgh recommendation to defer for 6 months and add "after last procedure". It was agreed that it would be unfortunate in the current climate of opinion to relax any advice on needles.

AIDS: a radical reassessment was necessary and Dr Gillon would canvass the Directors with regard to two possibilities. One was that the same countries should be quoted in respect of AIDS as for malaria with a six month deferral. The other was that the problems were now so widespread there was no particular merit in identifying African countries at all. Dr Gillon would undertake this task in the context of the draft AIDS leaflet for donors which he was preparing for the August meeting. *

Malignant diseases: it was agreed that if there was an established history of a tumour still being followed up, donors should not be accepted. In view of the difficulties experienced by BPL in 1985, Dr Gillon agreed to include in his alphabetical guide a comment to the effect that this was in the interest of the donor. Where the donor was not still attending a clinic the donor could be accepted subject to a written confirmation being obtained from the responsible doctor that the donor had been discharged as cured from follow-up. *

It was agreed to consider whether the guide should be put on to computer ultimately, for access by all Centres. *

3. SAFETY IN HEALTH SERVICE LABORATORIES: HEPATITIS B
Deferred from 25 February

This item concerned a supplementary report which had been prepared by the Group (chaired by Dr Bruce Cuthbertson) who had prepared for the Directors a paper on the testing of blood donations for hepatitis. This supplementary report considered the monitoring of hepatitis B testing at Transfusion Centres.

After discussion it was agreed to ask Dr Bruce Cuthbertson to prepare the following two papers: *
a) **for 20 May:** a paper on QA in relation to the PFC requirements for plasma screening for HBs Ag and HTLV III antibody. Dr Cuthbertson should record the current QA arrangements used by the Centres, define the residual requirements for the PFC and make recommendations to resolve these problems. Dr Perry would ask Dr Cuthbertson to write the paper.
b) **for 1 July, Supply and Demand:** a paper on QA for antibody quantitation. This too would review the current position, state the problems and make recommendations.

It was recognised that Dr Mitchell had made a development proposal in 1982-83 for a hepatitis QA laboratory which had not been forwarded to the CSA for consideration. It was noted that any additional system introduced now would in all likelihood have to be done without additional resources.

4. CONFIRMATORY TESTING FOR HTLV III ANTIBODY

Dr McClelland welcomed Dr E A C Follett and Dr John S Peutherer for this item. Dr Peutherer tabled the following:-
a) an analysis of confirmatory tests for HTLV-III
b) the text of a poster describing the Western Blot test

They explained that there was strong evidence to support the UK need to use the Western Blot as the final confirmatory test. Both reference centres were using purified antigen from NIH, and from Du Pont. Dr Peutherer tabled an analysis of confirmatory tests being used by the reference laboratories in the UK at March 1986 and noted that there was strong support developing for the Western Blot although so far few confirmatory labs were doing it.

Experience of the Wellcome screening test was that no reference laboratory had yet received any samples which proved to be false negatives when re-tested by the Western Blot. The Directors present recommended to Dr Follett and Dr Peutherer that a meeting should be arranged with staff undertaking screening to agree criteria defining which serum samples should be referred to the reference laboratories to permit further investigation of "grey zone" results. *

It was noted that more screening tests were expected to come on the market during 1986. It was noted that the view had been expressed at a recent WHO meeting that a satisfactory evaluation of a donor screening test must include a large number of donor samples. The NBTS/SNBTS were ideally situated to evaluate tests on this scale. There was some concern about relying on a single manufacturer and it was agreed that it is advisable to evaluate, as soon as possible, an alternative system which avoids the high rate of false positives produced by the Abbott test.

After discussion it was agreed that Dr McClelland should approach Du Pont (whose representative was due to meet him shortly) and ask the company to fund an evaluation. It would probably be necessary to employ someone for a full year to undertake initial evaluation and confirmatory test studies, this person probably to be outposted from a Transfusion Centre to a reference laboratory. *

5. DATA PROTECTION ACT 1984

a) Subject access to personal health data

The Transfusion Directors had had an opportunity to comment on a discussion paper (circulated late in 1985) by an inter-professional committee established by the Secretary of State to recommend the content of an order to restrict access to health data. It had been intended to discuss the matter at a meeting, but this opportunity did not arise and Miss Corrie had sought views by telephone and in correspondence. She had been able to report to the SHHD on donor data because the Directors had agreed unanimously that donors should have access to computer-held data on them. There was less unanimity on patient data and an opportunity to discuss this had not arisen in time to submit views to the SHHD. In the circumstances Miss Corrie undertook to ask the SHHD to note that the Blood Transfusion Service did hold patient health data on computer and that they should bear this in mind. *

b) Seminar at TPH, 23 April

Dr Mitchell reported on the seminar which he and Dr Perry had attended along with other BTS staff. It was noted that a minimal training package would be circulated shortly by the Personnel Officer: this comprised a series of overhead projector transparencies, some booklets about the Data Protection Act printed by the Registrar and a copy of the 8 principles.

It was agreed that staff using computers and micros should be asked to sign confidentiality documents in order to conform with the Act. Miss Corrie agreed to draft one based on a document which she had obtained from the ISD and on one in use in W Scotland BTS. She agreed also to write a paper on the Data Protection Act for the August issue of Bloodletter. *

Some Directors felt there was a need for a CSA policy on confidentiality in general and agreed the matter should be discussed first in a Co-ordinating Group. *

6. EC DIRECTIVE ON PRODUCT LIABILITY

Dr Cash had sent to each Director on 19 February 1986 a copy of the DTI explanatory and consultative note "Implementation of EC Directive on Product Liability". Dr McClelland, Dr Perry and Dr Yap had written to Dr Cash with comment and the letters had been circulated. Mr A J Murray's letter to Dr Cash concerning the position of blood donors had also been circulated.

It was agreed after discussion to accept an offer from Mr McCubbin, Scottish Health Service Legal Adviser, to attend the 20 May Co-ordinating Group and go through the Directive with the Directors. * Miss Corrie would arrange this and would send to Mr McCubbin the letters from Dr McClelland and Dr Perry to alert him to the problems which the BTS Directors foresaw.

7. ADDITION OF NON-DIRECTOR STAFF TO CO-ORDINATING GROUP MEETINGS
Deferred from 25 February.

Dr Urbaniak's letter of 4 November 1985 to Dr Cash had been circulated.

It was agreed that in principle Directors should not send deputes to meetings but that it should be open to them to bring members of their staff with them to "single topic" meetings and to invite them to attend for specific items on other occasions. *

It was agreed to ask Dr Urbaniak at the next meeting to clarify his problem. *

8. MINUTING OF FUTURE MEETINGS

Dr McClelland explained that Mrs Porterfield would attend future meetings to assist by taking minutes and this was welcomed by the

Directors present.

9. EVALUATION OF THE WELLCOME ELISA TEST FOR HEPATITIS B

Dr Mitchell had agreed at the meeting on 25 February to prepare a protocol for an evaluation of the Wellcome ELISA test for hepatitis B and he had sent this to the Directors on 17 April 1986. He tabled copies of the Wellcome test procedure (VK 20/21 of April 1985).

Mr Barr of W Scotland BTS had already contacted each Centre to ask if anyone wished to contribute difficult samples to the evaluation. None had been available, but Dr Mitchell had sufficient samples in his own Centre to prepare a panel of difficult positives. He had received no comments from the Directors on the protocol, which contained three phases. The first would commence 12 May, the second 19 May and the third 2 June, each to last one week.

There was discussion on the cost of the study. It was agreed to avoid becoming involved in contract evaluation and for that reason the Service would accept kits from Wellcome, but would not make a charge on the company for the evaluation which was in the interest of BTS as well as Wellcome.

9. DATE OF THE NEXT MEETING

Tuesday 20 May 1986.