

~~IN CONFIDENCE~~

SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE

Minutes of a Directors' Meeting
held in the HQ Unit on 10 June 1987

Present: Professor J D Cash (in the chair)
Miss M Corrie (Secretary)
Dr E Brookes
Dr D B L McClelland (except 3e to 3gi inclusive)
Dr Morris McClelland (items 1 to 7)
Dr R J Perry
Dr S J Urbaniak
Dr W Whitrow
Dr John Forrester, SHHD
Dr Ian Fraser (items 1 to 7)
Mr John Francis

1. INTRODUCTION AND APOLOGIES FOR ABSENCE

Action

There were apologies from Dr Gunson, Dr Mitchell and Mr Murray.

JDC introduced an additional item namely the Tayler Report on AIDS.

2. MINUTES OF THE PREVIOUS MEETING

The minutes of the meeting held on 3 March 1987 had been circulated and the following amendments were approved:

- a. Surrogate testing for NANB (3f)
Replace the second sentence by 'A modified proposal for a study now included the Edinburgh Transfusion Centre'.
- b. SNBTS clinical trials (3i iii.)
The final sentence to be amended to read 'It had been agreed that if Crown immunity was to be maintained then a substitute registration proceduremight be required'
- c. Guidelines for emergency cover at nursing homes approved for abortion (4)
The second sentence to read 'This second category was 2 units of O Rh neg blood earmarked for the nursing home and (for special risk cases) 2 units of crossmatched blood held at the nursing home, hospital blood bank or private laboratory'.

3. MATTERS ARISING

Actiona. Developments with the Private Sector (3a)

i. **Agreements:** Miss Corrie reported that Murrayfield was the only hospital not to have signed. CSA General Administrator was pursuing the matter and Miss Corrie undertook to exert pressure on him.

MC

ii. **Handling and laboratory charges:** Miss Corrie explained that she was trying on behalf of the SNBTS to obtain approval for 1 October as a common date for revising handling charges for product and laboratory services.

MC

JDC explained that DHSS colleagues appeared to be sympathetic to the idea of a UK consolidated system for establishing handling charges but the CBLA could not guarantee to adhere to whatever might be agreed. In the circumstances it might be necessary to have a Scottish system instead and JDC was pursuing the matter.

JDC

b. AIDS (3b)

i. **Dry heat treatment - patent:** Dr Perry understood that the CBLA had been approached by the Sinai Medical Centre (the patent holder) to apply for a royalty-free agreement for the NHS. CBLA appeared unwilling to do so and, apart from the fact that they appeared to be taking legal advice, it was very difficult to discover exactly what they were doing.

ii. **Viral inactivation in immunoglobulin products:** Dr Perry reported that the PFC had spiked the pH4 pepsin step in immunoglobulin preparation with live HIV virus and had documented a 4-log reduction in the virus titre. He had submitted the results in support of a licence variation and agreed to send these to Dr Forrester. IV immunoglobulin spiked with HIV virus showed inactivation of 3 - 4-logs during storage. Studies were in hand to improve the drying cycle of immunoglobulin products to make heat-treatment possible and they were considering introducing heat-treatment to the intramuscular immunoglobulins. This would require careful trials since the conventional approach was not to heat-treat intramuscular products.

RJP

RJP would report again in due course.

RJP

iii. **Current status of HIV antibody positive donors:** The current number of HIV antibody positive donors was reported as follows:

North	1
North East	0
East	3
South East	11
West	7
Belfast	3

Action

- iv. Seroconversion of previously ELISA+, WB- donors: A recommendation to the EAGA by its Screening Sub-Group had been circulated and JDC explained that EAGA had accepted it subject to an amendment in paragraph 5 which had been marked on the circulated paper. The recommendation was the same as that made by the Scottish Directors.
- v. Donor self-exclusion literature:
- * DHSS draft leaflet: The latest DHSS draft and the accompanying paper to a recent meeting of the EAGA had been circulated with the agenda. It was noted that the DHSS did not include donors who had had sex with prostitutes.
- JDC undertook to find out when the DHSS would issue their new self-exclusion criteria so that Scotland could be prepared for any press enquiries. JDC
- The Scottish Directors would review their criteria at the August meeting of the Co-ordinating Group. MC
- The Scottish Directors agreed to discuss at the August Co-ordinating Group meeting the problems of knowing what was actually being said in interviews at donor sessions and the reasons. MC
- It was important to receive soon the guidelines to session staff which Dr Brookes and Dr Gillon were drafting. EB
- Dr Mitchell had written that donors were indicating to him that cities such as Edinburgh, San Francisco and New York were no more or less dangerous than some places south of the Sahara. This would be considered in revising the Scottish criteria. MC
- * Scottish study: Professor Leather of Strathclyde University's Department of Marketing had prepared a proposal which the Scottish Directors had asked him to modify. Scottish Directors would discuss the revision at the August Co-ordinating Group meeting. MC
- vi. HIV epidemiological study: Dr Wallington (who had been due to send details of this study to JDC) had omitted to do so but they would arrive soon.
- vii. Dr Gunson's studies: In Dr Gunson's absence Miss Corrie undertook to ask him for a report in writing should he be unable to attend next time. MC
- viii. Donor attendance figures: A graph showing donor attendances from 1983 to 31 March 1987 had been circulated. Attendances in Edinburgh, Inverness and Glasgow were decreasing from a high point in 1986 and Aberdeen and Dundee had begun to recover from their low point in the same year. It was noted that the SNBTS as a whole had declined by about 2% since 1985.
- Miss Corrie would produce an update in six months' time. MC

ix. **HIV2:** A paper to the 19 May meeting of EAGA by Professor A A Glyn (PHLS AIDS Centre) and Dr McClelland's notes on the UK RTD's AIDS Working Group of 5 May and an Asglo-French meeting at PHLS on 12/13 May had been circulated.

Action

It had been agreed that large-scale testing for HIV2 was not justified at present but that there was a need to study donors with African associations in a pilot study which was being arranged. The EAGA would discuss the matter again and JDC would report. Meanwhile, he was preparing advance estimates for the SNBTS and would include HIV2 antibody testing on the basis that double testing would incur double the present cost.

JDC

Dr Perry was hoping that Professor Robin Weiss would let the PFC have the HIV2 strain so that they could undertake virus inactivation studies.

x. **HIV antigen testing:**

* **Routine donation screening:** The Scottish Transfusion Directors had decided at their Co-ordinating Group on 12 May that (on the existing evidence) it was not appropriate to commence routine antigen screening.

* **Anti-D cell donor accreditation:** Dr Urbaniak had circulated revised guidelines for donor accreditation (revised to take HIV antigen testing into account) and he spoke to these.

After discussion, the Scottish Directors agreed to consider at their next Co-ordinating Group meeting the aspects of the report which covered matters other than HIV antibody.

MC

Dr Urbaniak undertook also to draft a new document covering the possibility of wives being boosted by their husbands and including a report on the register and the way in which it was operating as well as the latest PFC yields. This would be discussed also at the Co-ordinating Group in the first instance.

MC

Dr Mitchell had sent comments and Miss Corrie would circulate these to Dr Urbaniak.

MC

xi. **Draft Tayler Report:** JDC had tabled extracts from a report by a Scottish Working Party chaired by Mr Winston Tayler (General Manager Lothian Health Board) to advise on the best way of providing services for patients infected with the virus responsible for AIDS. It was confirmed that none from the SNBTS had been on the Working Group.

The report included a recommendation that small Health Boards might wish to utilise the counselling services currently available in Regional Transfusion Services.

Miss Corrie undertook to seek the views of Dr Brian McClelland and Dr Mitchell and to include the matter in as early a Co-ordinating Group meeting as possible.

Action

MC

Secretary's note: Dr Mitchell and Dr McClelland both said subsequently that they did not wish 'at risk', worried well or HIV positive individuals (para 4.6.7 of the Tayler Report) to be referred to the BTS counselling services. JDC has taken steps to advise the GM of Directors' views.

d. Autologous Transfusion (3d)

i. **NBTS:** The second draft of the report of the Autologous Transfusion Working Party had been circulated. Appendix C of these guidelines included instructions on how to take blood. These were omitted from the Scottish version because in the four participating Regions the SNBTS would be withdrawing the blood.

Dr Brookes drew attention to some problems in these guidelines and agreed to write on a personal basis to the author of the report, Dr Lee of the Lancaster Centre.

EB

ii. **SNBTS:** It was noted that provision for autologous transfusion was to be established in the Inverness, Aberdeen, Dundee and Edinburgh Centres and that operational guidelines had been agreed for this pilot scheme.

Dr Mitchell had written that the BTS Sub-Committee had been informed that the Scottish guidelines would be finalised and issued (through the SAC in Haematology) to all Scottish haematologists. The Scottish Directors did not recall this but they had agreed that JDC should send a copy to the haematologists in the West of Scotland who were involved and he had done so.

On behalf of Dr McClelland, JDC reported that 11 patients had been referred to the Edinburgh Centre who had rejected one, assessed the remaining ten and rejected four of these. Problems included late referral and clinicians' failure to send crossmatched samples.

e. Private Blood Collection Agencies

i. **CSA/SHHD:** The position as recorded on the agenda was noted.

ii. **UK Conference of Royal Colleges and Faculties:** This conference supported the Scottish Directors concerned and had asked JDC for further information.

iii. **BMA:** The Scottish Secretary of the BMA had written that his organisation would be prepared to support regulation to control private collection agencies but not to make them totally illegal. JDC explained this matter was still to be debated in the BMA.

Dr Mitchell's written comments were noted.

Actionf. Unrelated Bone Marrow Donation (3e)

Dr Fraser reported that the parent group had met to consider papers on recruitment (Dr Gillon) and tissue typing technology (Dr Bradley). Experiments had shown that DNA technology could be applied in any tissue typing laboratory and that each Transfusion Centre could store its own DNA materials.

The group had agreed that it would be sensible to establish a combined panel of bone marrow and platelet donors. They would consider at their next meeting a suggestion for maintaining the register of donors through linked microcomputers with central co-ordination.

Two Welsh businessmen had launched an appeal for £1.3 million to establish a bone marrow donor panel and were in contact with the Welsh Office and the Cardiff Transfusion Centre, their plan being to have 100,000 Welsh blood donors tissue typed for a panel in Wales. Disappointment with the Anthony Nolan Panel was one reason for their initiative. Dr Fraser, JDC and Dr Morris McClelland would meet on 12 June the two gentlemen concerned (Mr Thomas and Mr Humphries) with DHSS representatives and JDC would inform the Scottish Directors of the outcome.

JDC

g. Surrogate Testing for NANB (3f)

i. UK study: It was confirmed that the minute of the previous meeting was incorrect and that the Edinburgh Centre are contributing to this study. Dr Gunson's letter of 27 April to JDC and the latter's reply were both noted.

ii. Cost of participation by the Edinburgh Centre: Mr Francis would confirm the figure and it was noted that Dr McClelland would probably apply to the next meeting of the Chief Scientist Organisation for a research grant in the first instance. It was agreed not to make bids against non-recurring funds meantime.

JF

RTDs

Directors noted the need for synchrony with England and Wales.

RTDs

h. Product Liability (3g)

i. SNBTS: The attitude of the SHHD was noted.

ii. NBTS: Dr Fraser had reported by letter that he would put the matter on the agenda for a forthcoming meeting of English Directors.

iii. DHSS/NBTS Advisory Committee: JDC had written in 1986 to Dr Harris of DHSS to have the matter discussed in the Advisory Committee, but Dr Harris had not done so.

i. Product licences (3h)

Dr Forrester reported that it was unlikely that the SNBTS would be required to hold product licences. JDC explained that this view

Action

appeared to be at variance with advice given by the Health Service Legal Adviser. JDC was pursuing the matter via the Agency's General Manager.

JDC

j. SNBTS Clinical Trials (3i)

i. Proposed 'teach-in' (clinical trials): Dr Perry was hoping to rebook this for the autumn of 1987.

i. Compensation for Z8 trial: In Mr Murray's absence Dr Forrester explained that the SHHD had extended the Treasury Compensation Scheme to Z8.

iii. Compensation on a wider basis: Miss Corrie and the CSA Secretary were working together on draft proposals for revision of the current compensation schemes. Dr Forrester recommended that the Agency should get the ABPI guidelines extended to cover all SNBTS products for all trials involving volunteers of any product given for non-therapeutic reasons.

k. SNBTS Assistance to NBTS: Anti-D immunoglobulin (3g)

Dr Perry had been informed at a recent CSA/CBLA meeting that labelling would present difficulties and that the shortage of albumin and anti-D in England/Wales would be of such a short duration that there was insufficient time for Scotland to help. They were therefore seeking alternative solutions. Dr Fraser expressed his concern at this statement.

PFC had offered to provide IV anti-tetanus immunoglobulin but this was not needed either.

l. CBLA/CSA Monoclonal Antibody RhD Cell-lines (3k)

Dr Perry explained that the CBLA/CSA collaborative agreement for cell-lines from UKTS was now acceptable to both parties. Once problems about obtaining specifications for cell-lines had been resolved the CBLA Director would try to obtain them for the PFC.

Dr Mitchell's comment (that his Centre would proceed with the possible reduction of anti-D cell lines using traditional 'Dorothy Crawford' type technology) was welcomed.

m. NEQAS (3l)

i. Advisory panel for haematology: The panel had agreed to the BBTs nominating a representative.

ii. Resumption of NEQAS blood group serology programme: This programme was due to move in September 1987 to NIBSAC but it was uncertain this would happen. The DHSS had been informed of the importance of it being revived but the NHS in England and Wales were not committed to it.

Dr Mitchell had reminded the Directors of his earlier proposal to offer a QA scheme to Scotland and the Directors agreed to consider this at the November meeting of their Co-ordinating Group. JDC would obtain the protocol from Dr Mitchell meanwhile.

Action

JDC/MC

n. Guidelines for Emergency Cover at Nursing Homes approved for abortion by the Secretary of State (4)

Dr Brookes had drafted revised guidelines which she had issued to the Scottish Directors for comments. She would incorporate the comments and bring a revision to the August meeting of the Co-ordinating Group. (Dr Mitchell had written that he would like SHHD advice about the Stirling Nursing Home but Dr Forrester was awaiting the revised guidelines before he could help).

EB/MC

o. Minimum Age for Donation

Miss Corrie reported that she was preparing a paper with Dr Brookes which she would put to the RDOs in July and to the Scottish Directors in September.

MC

4. NBTS DIRECTORS' MEETING 15 APRIL

Dr Whitrow spoke to his notes (which had been circulated). Miss Corrie explained that the EEC rules on drivers' hours did not apply to the BTS which was governed by the domestic rules. That there was a written Scottish document on drivers' hours which each Unit Administrator had and it would be on the agenda of the next Unit Administrator's meeting. She undertook to ensure that each Director (as well as Unit Administrators) received a copy of the regulations as they applied to the BTS.

MC

5. SUPPLY OF BLOOD TO BRITISH NATIONALS OVERSEAS

a. Dr Contreras' Letter

A copy of Dr Contreras' letter to Dr Fraser of 9 March 1987 had been circulated.

b. SNBTS

JDC had (on behalf of the Scottish Directors) asked Dr Contreras to expand on her letter and had learned that it concerned in particular embassy officials who wished to take bags and/or details of their blood groups abroad.

Dr Urbaniak reported that oil companies in his Region participated in an international scheme enabling them to receive blood through this organisation when abroad.

After discussion it was agreed that each Scottish Director should meet individual reasonable requests in respect of high-risk areas for AIDS as they felt appropriate and JDC would notify the CSA General Manager accordingly.

TDS/JDC

Action

6. COMMERCIAL BLOOD PRODUCTS

a. Purchases year to 31 March 1987

Dr Forrester tabled details of commercial products purchased by the Scottish Health Boards (which he had obtained through the CSA General Manager). These omitted items bought by Dr Urbaniak for the Grampian Health Board and Dr Urbaniak would send details to Dr Forrester. That apart, the purchases (excluding VAT) had been £348,875 against £308,014 in the previous year.

BTS would have to try to find out what stocks were being held in Glasgow. For example, one hospital was refusing delivery of SPSS because of overstocking while another had purchased commercial product.

There was a need to develop a PFC product for FVIII patients with inhibitors. RJP

JDC thanked Dr Forrester and would thank the CSA General Manager. He would also arrange to meet colleagues from the Greater Glasgow Health Board. JDC

It was acknowledged that the purchases were not high in comparison with England and Wales.

b. Ordering by BTS

Dr Forrester said that any influence by the SHHD in getting agreement that commercial products which were needed would be ordered by the SNBTS would be counter-productive and represent interference in the Health Boards' activities.

7. DONOR HAEMOGLOBIN TEST

A proposal from Dr Entwistle of the Oxford RTC (for a trial in which pre-donation copper sulphate tests would be abandoned and retrospective screening substituted) had been circulated.

Dr Entwistle had since reported that a number of major transfusion centres in Europe did not undertake pre-donation testing. It was noted that the idea appealed to Dr Mitchell who suggested a study.

After discussion it was agreed not to change, in the interest of donor health care and of preserving existing product specifications. JDC would notify Dr Entwistle. JDC

8. UK REGISTER OF RED CELLS

It had been agreed that Dr Mitchell would report annually in June. He had written to JDC that he had sent his usual monthly report and had nothing to add to that. However there might be a problem about supply of cryo-stable bloodbags which were used for the liquid nitrogen bank. Miss Corrie to write to Dr Mitchell for more information about the current supply and alternative sources. MC

9. DATE OF THE NEXT MEETING

6 October 1987.