

IN CONFIDENCE

SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE

Minutes of a Directors' Meeting held
in the HQ Unit on 25 March 1986

Present: Dr J D Cash (in the chair)
Dr E Brookes
Dr D B L McClelland (except 3a and part of 3i)
Dr W M McClelland
Dr R Mitchell
Dr R J Perry
Dr S J Urbaniak
Dr W Whitrow
Miss M Corrie (Secretary)
Mr J N Francis
Dr I Fraser, Bristol
Dr J Forrester, SHHD

1. INTRODUCTION AND APOLOGIES FOR ABSENCE

Dr Gunson, Manchester and Mr A J Murray, SHHD, had sent apologies.

2. MINUTES OF THE PREVIOUS MEETING

The minutes of the meeting held on 10 December 1985 had been circulated and Dr B McClelland had submitted a comment. See item 3 (c) i below.

3. MATTERS ARISING FROM THE MINUTES

a) Developments with the private sector (3a)

Dr Cash's letter of 6 March to CSA General Administrator had been circulated. This requested that the Directors should have an opportunity to meet the CSA Chairman, Mr Morison, SHHD and senior CSA officers concerning the agreement with the private sector. There had been no response, either in writing or verbally.

The Directors had been surprised at the February BTS Sub-committee meeting by the Convenor's attitude towards a particular clause in the draft agreement and his proposed alternative (which he had tabled).

The matter of consultation with trade unions was discussed also. It appeared that only ASTMS had been consulted despite its being a minority union in the SNBTS. The Directors felt that if the contents of the agreement were to be revealed at all to trades unions then each should have an opportunity to see it. Dr Mitchell reported that ASTMS had met recently in his Centre and that copies of the draft agreement appeared to have been available to all members of the union.

Dr Cash had asked when TDs could take action on the new final draft in order to discuss with local private hospitals. He had been told that this would not be appropriate until ASTMS had responded.

The Directors noted also that this delay was depriving the NHS of income from the private sector.

The Directors agreed to support Dr Cash's request for an urgent meeting with the CSA Chairman and senior officers from the CSA and SHHD. Dr Cash undertook to convey this to the Chairman. *

b) AIDS (3b)

i. viral contamination of product: Dr Perry explained that a firm collaborative study between PFC, Professor Weiss and Dr Peutherer was now underway and that a member of Dr Peutherer's staff had been seconded to Professor Weiss's laboratory. The first experiments were due to take place in the next few weeks. The study included BPL processes also.

The DHSS Medicines Division had informed Dr Perry that they had asked licensed manufacturers of immunoglobulin to provide HTLV-III and other virus inactivation data by 1 July 1986.

(Dr B McClelland arrived at this point).

The Medicines Division had also stated that all products issued after 1 July must be from validated (HTLV-III) plasma and that they required details of the methods used to test for HTLV-III and hepatitis B.

The Directors agreed to continue to operate the SOP agreed at the special Co-ordinating Group Meeting on 16 January, acknowledging the operational difficulties of so doing. There were however no major problems of supply at the present time. *

Dr McClelland drew attention to the fact that the requirement under the SOP to recall product which might subsequently be re-issued presented public relations problems and wondered whether his colleagues might agree a standard approach to clinicians. It had already been agreed in respect of anti-D that the BTS would not indicate reasons for withdrawal. It was underlined that the BTS were concentrating on following-up patients who received known contaminated (HTLV-III) donations. Apart from the need to inform clinicians treating hypogammaglobulinaemic patients the Service would not follow up patients receiving suspect (HTLV-III) product from fractionated plasma.

On the matter of tracing recipients of anti-D (Co-ordinating Group 6 December 1985 item 15 b iv and 25 February 1986 item 3 f) Dr B McClelland had sent his protocol to Dr Brookes and Dr Mitchell as agreed. He had discovered in respect of his own region that the prevalence was too low for an epidemiological study and this would pertain in the East region also. Dr Mitchell agreed to examine whether it would be possible to undertake the study in the West. *

The NE Region might provide sufficient cases and Dr McClelland undertook to send the protocol to Dr Urbaniak.

ii. donor screening in US military establishments: The Commander of the US Forces in the UK had asked the NBTS to inform commanding officers of donor servicemen/women who were AIDS antibody positive. The Transfusion Service in England and Wales had refused on the grounds that they intended to treat all donors identically. As a result the DHSS had told the US military authorities that the latter's proposals were not acceptable.

Dr Mitchell and Dr Brookes had held sessions recently at US Military bases and had reported no problems. It was understood that the US authorities were about to arrange for all serving men and women as well as new recruits to be tested for the AIDS antibody.

Dr Urbaniak had heard that the oil companies wished to arrange for antibody testing of new recruits. It was agreed this would not be done by BTS.

Dr Cash reported that the Scottish reference centres were obtaining very interesting results from their comparison of the Western Blot with other methods. He hoped that representatives would attend the special Co-ordinating Group meeting on 30 April to report their findings.

iii. counselling: It was noted that Dr Cash had arranged a seminar at the HQ Unit on 14 May for staff with experience of counselling donors. Dr Urbaniak complained that the date had been fixed without consultation and that no one from Aberdeen could therefore attend.

The Directors reported the current status of antibody positive donations as follows:

| | |
|-----------|---|
| Aberdeen | 0 |
| Belfast | 1 |
| Dundee | 3 |
| Edinburgh | 4 |
| Glasgow | 2 |
| Inverness | 1 |

iv. UK discussions on antibody testing: It was reported that NIBSC intended to establish a group which would include discussion on this topic and that this Group's interests might clash with the Group chaired by Dr Mortimer. It was agreed that the SNBTS should give fullest support to the NIBSC Group.

c) SNBTS nationally-sponsored clinical trials (3c)

i. system for studying adverse reactions: Dr McClelland could not recall having agreed to give attention to a system for studying adverse reactions to new products. Dr Cash confirmed that the suggestion had arisen from a letter Dr Crawford had sent to Dr Cash and which had been discussed as item 7 of the October 1985

Directors' Meeting. Dr McClelland had suggested at that meeting that there was a need for such a system and had agreed to propose one.

It was agreed instead that Dr Cash and Dr Perry should meet trial co-ordinators once a year and ask them to summarise the nature and status of each trial and any adverse reactions. Dr Cash would organise this. *

ii. coding system: Dr Perry tabled a paper which was welcomed and accepted.

d) RH phenotyping (3d)

Dr McClelland and Dr Whitrow had asked to discuss this item, which had been discussed briefly at the Directors' meeting on 2 October 1985, when those Directors present, with the exception of Dr Brookes, had welcomed moves to designate Rh(D) negative blood on the basis of r' and r" only. Dr Brookes had felt it appropriate to reserve Dundee's position until computer developments were nearer introduction in her Centre. It had been further agreed (unanimously) that all Du donors should be regarded as Rh(D) positive. The current position was reported thus:-

Defining such donations as Rh-: Aberdeen and Inverness

About to do so: Edinburgh

Awaiting computing developments: Dundee

Operating in traditional mode: Belfast and Glasgow

e) HLA antisera screening (3f)

As reported at the previous meeting Dr Yap of the Edinburgh Transfusion Centre had attended a UK transplant workshop dedicated to HLA reagent procurement. Dr McClelland tabled Dr Yap's summary of the meeting.

It was noted that the report did not supply the information which the Directors had sought.

Dr McClelland undertook to write to Dr Bradley of UK Transplant for the information required. *

f) HTLV-III epidemiological study (formerly Dr Tedder's HTLV-III project) (4)

Dr Tedder's suggested protocol for investigation of seropositive donors and the recipients of putative infective blood had been discussed and welcomed at the previous meeting and Dr Cash had undertaken to notify Dr Gunson that the Scottish Directors

supported Dr Tedder's proposal (which they felt should be national) and that they would participate as far as possible.

In Dr Gunson's absence Dr Fraser reported that a working party had been established with Dr McClelland as a Scottish member. They had agreed to continue co-operating with the MRC.

Dr Tedder would apply for an MRC grant for 1986-87 to study the epidemiology of donors and all recipients of blood/products retrospectively for 5 years. Dr Wallington of Bristol (who had been appointed the group's co-ordinator) had obtained a protocol for the purpose from the USA which the group would have a chance to study.

It was noted that the consultants in charge of recipients would have to be contacted via Transfusion Centres.

The Scottish Directors supported the proposal on the basis that they could see and agree the protocol prior to implementation. Dr Cash would ask Dr Wallington for it. *

g) Notes on Transfusion (6)

At their January 1986 meeting the English Directors had agreed unanimously to ask Dr McClelland or Dr Urbaniak to take over the main revision of "Notes on Transfusion". Dr Cash had approached Dr Urbaniak but he had declined due to pressure of existing commitments. Dr McClelland had subsequently agreed to undertake this task. His colleagues in the enterprise would be Dr Martlew of Manchester, Dr Trenchard from Cardiff and another Transfusion Director: Dr Fraser had offered his services.

h) Directed donations and autologous transfusion (8)

A report on autologous blood transfusion from a working group of the NBTS Advisory Committee had been circulated together with Dr Fraser's covering letter.

Dr Fraser explained that the DHSS had asked the NBTS Advisory Committee's opinion as to whether the NHS should consider autologous transfusion in the light of a possible private service being established in London. The paper was due to be considered at the next NBTS Directors' meeting.

Dr Cash turned to the recommendations which were discussed as follows:

- (1) Supported/agreed
- (2) Agreed
- (3) Yes, where clinically suitable
- (4) Agreed
- (5) Agreed
- (6) Agreed, on the basis that storage facilities for autologous transfusion within the private sector might lead the latter to establish non-autologous transfusion service.

Generally the Scottish Directors felt that autologous transfusion should be used where there was a perceived benefit to patients which could not be achieved in any other way. They did not agree that district general hospitals should collect, label and stored units, feeling instead that regional Transfusion Centres maintain this programme.

i) Unrelated bone marrow donors (9)

Dr Alan Burnett's further letter of 31 January 1986 had been circulated. It had been considered at the Co-ordinating Group meeting on 25 February, when the Directors agreed they would attempt to contribute and had asked two BTS consultants to prepare proposals for their consideration. This was a reversal of a previous decision. Dr Urbaniak asked for evidence of the need to change. Dr Fraser explained that a European BMT group had recently stated that it would be of value for transplanters to look to unrelated donors. It was noted also that there were two large studies underway in the USA and there was an expectation of success.

It was noted that the current UK position was as follows:-

UKTS: This service did not charge for a search. It had a panel of 9,000 donors, 6,000 of which had come from Bristol and the remainder from seven other Transfusion Centres.

Anthony Nolan panel: This charged £80 per search and had a panel of 15,000 donors.

Some donors were probably on both panels. Representatives of the UKTS and the Anthony Nolan panel had met recently and agreed as a result not to merge.

The Directors reaffirmed their intention to explore the issue and awaited with interest a joint document from Dr Gillon of Edinburgh and Dr Ghosh of Dundee. However, they would wish to see development within the Blood Transfusion Service and Dr Cash undertook to convey this to Dr Fraser.

j) HTLV-III antibody testing of staff reagent samples (11)

The Scottish Directors had undertaken to consult staff and discuss this matter further at the 25 February Co-ordinating Group. Not all Directors were present however and the matter had been deferred to the current meeting.

The issue had been whether staff who donated blood for samples should be tested for the AIDS antibody. A reagent had been defined and options offered had been to test only donors whose blood was used for reagents was defined or to begin afresh by calling for volunteers to form a panel for any diagnostic purpose, the members of the panel being tested regularly for antibody.

Dr Mitchell reported that all donors for any reagent purposes in his Centre were now treated as if the donation was for a therapeutic intention and all samples were therefore tested. The Directors agreed that the WETS approach was soundly based and Dr Mitchell agreed to circulate his protocol to all Directors.

- k) 45% sodium citrate solution (12)
Dr Perry had reported at the previous meeting that the Haemonetics company had ceased to supply this product and he had agreed to produce it in response to a request from the Edinburgh Centre. Having asked the other Transfusion Directors about their requirements he was manufacturing very small amounts and the product would be issued on a named patient basis.

4. ENGLAND/WALES DIRECTORS' MEETING

Dr Brookes had attended the meeting on 22 January 1986 in lieu of Dr Whitrow and her note had been circulated with the agenda.

The following points were made in discussion:-

- a) Supply of hyperimmune plasma (anti-D and anti-tetanus)
Dr Fraser was invited to the SNBTS Directors supply and demand meeting on 1 July 1986. *
- b) AIDS update
Dr McClelland had now sent 4 positive plasmas to Dr Mortimer for national QA panel purposes.
- c) CMV hyperimmune plasma
The question had been asked as to whether the PFC could open wedge packs should English CMV plasma be sent in that form. Dr Perry reported that they could. From the 400 kg of plasma sent by BPL he had already produced 200 vials of product for return.
- d) Nurse-led donor sessions
It was expected that this study at the Brentwood Centre would continue for another year. While the results were promising, more information was needed.
- e) Blood donors from central Africa
The DHSS were considering another AIDS leaflet for donors. It was agreed that the relevance of central Africa required thorough discussion and other items needing revision were a definition of active homosexuality and the use of needles.

The Scottish Directors agreed to prepare another donor leaflet. Dr McClelland undertook to ask Dr Gillon of the Edinburgh Centre to prepare a draft. This should be ready for consideration by the Co-ordinating Group on 19 August 1986. Dr Fraser would be kept informed. *
- f) Training film for donor attendants
It was confirmed that each Scottish Transfusion Centre also had a copy of the film and the trainers' notes.

5. SURROGATE TESTING FOR NANB

The FDA Advisory panel's recommendation published in AABB Blood Bank Week 21 February 1986 had been circulated. It was noted that Transfusion Services in the US might soon be undertaking ALT and anti-core testing of blood donations to reduce the incidence of non-A, non-B hepatitis. Dr Forrester said it was highly unlikely that the UK Departments of Health would fund testing based on data from the USA, but it was recalled that HBs-Ag and AIDS antibody testing had both been introduced without prior UK research. Certain clinicians and haematologists in this country had felt that the Transfusion Services had been slow to commence AIDS antibody testing and others had similar views in relation to non-A non-B hepatitis surrogate tests.

Dr McClelland said he would be able to provide data about raised ALT levels in blood donors by the Autumn of 1986, following a successful Ethics Committee proposal. Dr Forrester would be glad to hear of any research but could not guarantee funding.

After a full discussion the Directors agreed to give consideration to funding someone to undertake research. Dr Cash would think about the possibilities in association with Dr Fraser and make some proposals to the Directors.

6. FUNDING OF FRACTIONATION OF PLASMA FROM NORTHERN IRELAND

Dr Cash reported that the SHHD had not funded in 1986-87 the sum which the CSA had requested for fractionating plasma from Belfast. The BTS had never been funded for Northern Ireland plasma and had now reached a stage at which they could not afford to increase fractionation beyond the level reached at March 1986. Income was received from Northern Ireland, but it went to the Treasury.

Dr Perry would contact Dr Morris McClelland to agree the upper limit of plasma which could be accepted and the products processed.

7. MEDICAL PROTECTION: AIDS ANTIBODY POSITIVE RECIPIENT

Dr Brookes reported that she had an antibody positive recipient of a donation from a donor whose previous donations had also been transfused and the recipients and their families were about to be told the situation. She had been advised by her consultant colleague in the cases to contact the Medical Defence Union. Her colleagues agreed that it was sensible to do so.

8. PRODUCT LIABILITY

Following receipt of a recent EC paper on proposed product liability Dr Cash had heard that it was possible that blood products would be exempt so that it would not be necessary to spend much time discussing the matter programmed for a Co-ordinating Group meeting on 30 April. Dr Cash had asked the CSA Secretary for the Agency's independent view on the matter.

9. DATE OF NEXT MEETING

25 June 1986.