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JDC0023

IN CONFIDENCE

SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE

Action

----- Minutes of a Directors' Meeting held in the HQ Unit -----
 on 12 April 1988

Present:

Prof J D Cash (In the Chair)
 Miss M Corrie (Secretary)
 Dr E Brookes
 Mr J N Francis
 Dr R Mitchell (Item 3b(ii) onwards)
 Dr W Whitrow
 Dr J M Forrester (SHHD)
 Mr T MacDonald (SHHD)

1. INTRODUCTION AND APOLOGIES FOR ABSENCE

There were apologies from Dr Brian McClelland, Dr Perry, Dr Urbaniak, Dr Gunson and Dr Wagstaff.

Dr Bruce Cuthbertson of PFC would attend for item 3e.

2. MINUTES OF THE PREVIOUS MEETING

The minutes of the meeting held on 8 December 1987 had been circulated and the following amendments were approved:

3h Product Liability and Product Licensing

Replace the last sentence of first paragraph by 'It was imagined that the Chief Pharmacist claimed that he was the licensing authority for Scotland'.

3j Guidelines for emergency cover at nursing homes approved for abortion

Second sentence to read 'These comments were discussed briefly then it was remitted to Dr Brookes and Professor Cash to take into account comments made by Dr Mitchell, finalise the guidelines and send them to Dr Forrester for comment without further reference to the Directors' meeting'.

3. MATTERS ARISING

a. Developments with the Private Sector (3a)

- i. **Annual Meeting:** It was noted that annual meetings between the Directors and the private hospitals in their regions had been held and that relationships were reported to be good and all requests from the private hospitals are acceptable. Miss Corrie had advised the CSA Director of Administration accordingly.
- ii. **NHS patients admitted to private hospitals:** This concerned the recent admission of NHS patients from Health Board regions to private hospitals in other regions in order to reduce NHS waiting lists. JDC had written to Mr Macniven of the SHHD of the need for forewarn the SNBTS in such cases. His letter had been acknowledged with a recognition of the problem and an undertaking to give forewarning in future.

The problems included the difficulty of ensuring that blood or blood products issued to private hospitals for NHS patients were not used for private patients. The formal position was that no handling charge was being levied by BTS.

A further problem was the commitment to reduce supplies to the private sector in times of shortage within the NHS: the admission of NHS patients to private hospitals complicated this. Finally, there was the overall problem of the NHS wishing to reduce waiting lists during a period when donor attendances had been declining.

b. AIDS (3b)

- i. **Heat treatment/AIDS validation studies:** It had been agreed previously that Professor Collee of Edinburgh University would inspect the facility at PFC and that if he was satisfied the validation studies could transfer to PFC. JDC reported that Professor Collee had inspected the PFC and approved the facility verbally. Dr Forrester explained that a submission from the CMO was with the Minister and a decision could be expected soon.
- ii. **Repeat ELISA reactive, WB negative donors:** JDC reminded the Directors of the EAGA advice which was that the first donation from such a donor should not be used. He/she should be recalled in 6 months. If the test results were the same as first time the donation should not be used and the donor's name should be flagged. If the donation was clear by both tests on the third occasion it should be used for therapeutic purposes. If however the third donation was ELISA positive and WB negative the EAGA advice was not to use the donation and to invite the donor, counsel him and advise him not to donate again for therapeutic purposes.

N
JF

The weaknesses in this were obvious and the Directors had been unhappy about operating such a system. The reasons included the fact that some such cases were proving negative using the Abbott test, that positivity was sometimes in fact an antibody to horseradish peroxidase and that it was very difficult to explain the position to a donor in terms that would be understood.

It was agreed to discuss the matter again in the Co-ordinating Group and define an SNBTS policy.

MC

- iii. Alternative testing: As instructed by the Directors JDC had written to the CMO that, especially in Edinburgh, the BTS suspected that the Transfusion Centre was being used by people who wish to know their HIV status. He and the CMO were now in correspondence about how to analyse the data which the BTS had produced. He would continue informing the CMO of the problem.

JDC

- iv. Current status report of confirmed HIV antibody positive donors: The Directors reported the following:

Inverness	2
Aberdeen	14
Dundee	5
Edinburgh	14
Glasgow	10
Belfast	3

- v. Anti-HIV 2 testing of blood donors: It was recalled that during 1987 Dr Gunson had invited all the Transfusion Centres to send to Dr Philip Mortimer of the PHLS the sera from selected donors for anti-HIV 2 testing. The criteria for selection of such donors had been circulated.

Dr Gunson had written recently to Directors to say that no Centres except 4 (which had been co-operating experimentally) had done so.

Dr Mitchell however had sent samples and it was believed that the Edinburgh Centre had agreed to do so also. In the circumstances Miss Corrie was asked to contact Dr Mortimer to establish the facts.

MC

c. Notes on Transfusion/Transfusion Medical Handbook (3d)

JDC understood that Dr McClelland was now editing this. It was agreed that the publication would be very important given the Consumer Protection Act and product liability.

d. BMA/BTS Forum on AIDS (3e)

- i. Discussion papers: As agreed at the last meeting Dr Perry had circulated to his colleagues his paper on research and Dr Gillon's on Autologous Transfusion.
- ii. The BMA: had agreed to let the Scottish Transfusion Directors see their final proposals for comment before publication.
- iii. Developments within the forum: There had been no meetings since the autumn of 1987 but the BMA had notified on 6 April that Dr Michael Illingworth had agreed to act as Chairman and would convene a meeting.

e. Surrogate testing for NANB (3g)

The SNBTS Microbiological Validation Group had been invited to reconsider to what extent it was necessary for every Centre to be involved in evaluating the technology for ALT testing and to report.

JDC welcomed Dr Bruce Cuthbertson, Chairman of the Group, who introduced a preliminary report (which had been circulated). The Eppendorff Epos (supplied by BDH) had proved highly satisfactory. It was user-friendly, gave good reproducibility of results and excellent comparability between the BTS regions.

It would be necessary to consider the status of donors found to be ALT positive, the repercussions of undertaking testing and the counselling problem. Dr Cuthbertson agreed that his group would assess the four systems currently available for anti-core testing.

BC

It was confirmed that it had been agreed not to introduce ALT testing in Scotland until it had become UK policy, but Directors wished to reserve their position on this matter in the light of reports of the commencement of ALT testing in at least one E/W RTC.

TDs

Meanwhile, imported commercial products were found to be marked 'material ALT tested'.

JDC recommended that the SNBTS should continue its current research. It was agreed to discuss the matter again at a Co-ordinating Group meeting.

MC

Miss Corrie would ask Dr Wagstaff to report at the next Directors' meeting what was happening in the English Centres and what research was underway there.

MC

f. Product liability and product licensing (3h)

- i. SNBTS: JDC's letter to the Superintendent Medicines Inspector (which had been circulated) explains the position. JDC reported that a new Inspector had been appointed and would visit a few Transfusion Centres mainly for educational purposes. There was a need to define which areas of RTC work should be inspected.
- ii. PFC licensing programme: A statement of the current licence status of PFC products and programme for licence applications had been circulated. The Chief Medicines Inspector had now visited the PFC.
- iii. Transfusion Centres: Miss Corrie was preparing a common nomenclature for RTC products. It was hoped to agree these at a Co-ordinating Group meeting soon. Then specifications would be prepared for approval. It was noted that the Chief Pharmacist had said the EEC were apparently attempting to solve the problems raised by RTC produced blood products in relation to product liability.
- iv. NIBSC/UK BTS Group: The four sub-groups and their Scottish representatives were noted to be as follows:

Specifications for RTC products (A Barr)

Reagents (Dr Cuthbertson and Dr Mitchell) + *M Brown*

Fractionated products (Dr Perry)

Microbiology (Mr Barr)

These sub-groups had submitted their draft reports to the parent group. The British Pharmacopoeia were taking an interest.

- v. Action being taken by CSA Headquarters: This included studying the possible need to amend contracts for supply of blood to the private sector (ie requiring private hospitals to take blood insurance) the storage of records of sale, product liability to Belgium patients receiving monoclonal HBs Ag the position of product liability for tear-down bags and indemnity to blood donors.

g. Age limits for blood donation (3k)

- i. Minimum: The Scottish Law Commission had proposed to the Government that the age of consent to medical treatment should be reduced to 16 and that this should apply equally to blood transfusion. Miss Corrie had written to the SHHD asking for the support of the SNBTS to be put to the Government. She had been assured this would happen.

- ii. Maximum: Dr Mary Inskip had reported as requested and all Scottish Directors had commented. It was agreed not to change the current SNBTS practice which was an upper limit of 65, with Directors exercising discretion in individual cases.

TDs

Miss Corrie to thank Dr Inskip for her contribution.

MC

h. PFC products for Factor VIII patients with inhibitors (31)

- i. New Factor IX: Dr Perry had hoped to launch this in June 1988. It was reported on his behalf that it was delayed through technical problems and that he would report to the Scottish Directors at their supply and demand meeting on 17 May.
- ii. Visits to Haemophilia Directors: Dr Perry and his colleagues had not yet visited the Haemophilia Directors. They were awaiting the return of a questionnaire which they had asked the Haemophilia Directors to complete first.

RJP/MC

It was noted that the consultation process would be speeded by the recent appointment of the Clinical Trials/Product Surveillance Manager.

4. NBTS DIRECTORS' MEETING

The minutes of the meeting held on 20 January had been circulated and were discussed.

Miss Corrie undertook to see that the Directors received copies of the Medicines Commission's advice to Health Ministers on healthy volunteer studies.

MC

5. BLOOD SUPPLIES TO GREATER LONDON

Dr Jean Harrison's 'Dear Colleague' letter of 1 February and accompanying questionnaire had been circulated. This asked Transfusion Centres with surpluses whether they would be willing to contract to send a specific number of red cells to one of the London Centres. The written comments of some Scottish Directors were also circulated.

JDC explained that the English/Welsh Transfusion Centres were now making great efforts to help the London Centres, who had sufficient supplies at present. In the circumstances it was agreed to delay an SNBTS decision until all the Directors were present.

MC

6. CO-ORDINATED STUDY OF TRANSFUSION-TRANSMITTED HIV INFECTION

JDC recalled that the Scottish Directors had asked Dr Robert Crawford to do a Scottish study. Dr Tim Wallington had then announced that he was undertaking a similar study on a UK basis and he had written recently to JDC to ask if the Scottish Centres would participate.

The Directors described the following experience in Scotland:

Dundee: Two patients infected by BTS products whose consultant was reluctant to be involved in a study.

Inverness: None

West: Two, one of whom had died.

Aberdeen: Nil

Edinburgh: 4

Belfast: None

Those Directors present agreed to arrange for the completion of Dr Wallington's forms as soon as possible.

TDs

7. ANTI-HIV TESTS ON NEW AND REPEAT DONORS

Dr Gunson had written to the Scottish Transfusion Directors to say that the information which they had supplied to him did not tally with the SNBTS annual statistics. The matter had since been resolved by the Directors individually with Dr Gunson. Miss Corrie to find out the position with Dr McClelland and report to JDC. Off agenda.

MC

8. DONOR TV/RADIO CAMPAIGN

Miss Corrie reported on the campaign. The TV one had run for 5 weeks from 14 February, aimed at lapsed donors. It had been accompanied in some regions by letters to such donors. The radio campaign lasted for 4 weeks and was addressed to regular, lapsed and new donors.

The response in donor attendances was favourable initially though not even throughout the country. Five weeks was a short period to compare accurately with previous years and a quarter was better in this respect.

A graph was tabled showing quarterly donor attendances for the years from 31 March 1984 to 1988. An upward trend in the final quarter of 1988 was noted.

Miss Corrie explained the analyses which were currently taking place. The Regional Donor Organisers and colleagues were working on how to improve the experience of donating blood in the hope of retaining donors who were returning. It would also be necessary soon to decide if any further media campaign was necessary.

9. RESCREENING OF HEPATITIS B POSITIVE DONORS

Professor Wright of Southampton University had proposed that the hepatitis B negative blood donors identified in his earlier study should be recalled to each RTC for a repeat blood specimen and a simple questionnaire relating to age, place of birth, tattooing, travel abroad and possibly sexual practices. He had agreed that individual blood donors would not be identified.

It was agreed that JDC should notify Professor Wright that each Director would consider the matter if Professor Wright wished to consult them individually. Miss Corrie to tell Dr Brian McClelland and Dr Urbaniak.

MC

10. BRITISH BONE MARROW DONOR APPEAL

One of the organisers of the above had contacted Dr Boulton in the Edinburgh Centre to notify a 'Bone Marrowthon' to be run in June from John O'Groats to Lands End with local marathons also. The appeal would send a mail shot to 20,000 Scottish school children. They were offering Scottish Transfusion Centres the chance to associate themselves with the endeavour.

After discussion it was agreed that JDC should contact the appeal's publicity agents to say that the Scottish Transfusion Centres did not wish to be associated with the 'Marrowthon'. Miss Corrie to tell Dr Urbaniak and Dr McClelland.

JDC

MC

It was confirmed that the Scottish position concerning unrelated bone marrow transplantation was that they were awaiting a report and recommendations from the UK Executive Group followed by DHSS approval. It was agreed to discuss in the Co-ordinating Group how Scotland could produce a panel of tissue typed donors for platelets and marrow once the principle was approved.

MC

It was agreed that any enquirers to the Transfusion Service during the 'Marrowthon' should be invited to become blood donors while the establishment of a NHS panel was under consideration.

11. DATE OF THE NEXT MEETING

14 June 1988.