

IN CONFIDENCE

SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE

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

Present: Dr J D Cash (in the chair)
Dr E Brookes
Dr R Mitchell
Dr S J Urbaniak
Dr W Whitrow
Dr P Foster (item 3b (i) only)
Miss M Corrie (Secretary)
Mr J N Francis
Mrs E Porterfield (Minutes)
Dr J Forrester (SHHD)
Mr A J Murray (SHHD)

1. INTRODUCTION AND APOLOGIES FOR ABSENCE

Dr Cash introduced Mrs Porterfield who would in future attend as minute taker.

Apologies had been received from Dr D B L McClelland, Dr R J Perry, Dr W M McClelland, Dr I D Fraser and Dr H H Gunson.

2. MINUTES OF THE PREVIOUS MEETING

The minutes of the meeting held on 25 March 1986 had been circulated and the following comments had been received.

Minute 3b - AIDS

i. viral contamination of product

Page 2, final paragraph, line 5 - should read ".... the prevalence was probably too high ...

Minute 3c - SNBTS nationally sponsored clinical trials

Concerning the first sentence the relevant minute (2 October 85) reads "after discussion Dr McClelland agreed to discuss this proposal with his colleagues and to comment in due course." Dr McClelland pointed out that he did not suggest the need or agree to propose a solution.

It was noted that a system for an annual review had now been established with Dr Perry (see minute 3c).

Minute 3d - Rh phenotyping

- i. line 5 - replace "r' + r" typing" with "D-typing"
- ii. Insert heading "r' + r" typing" above table of the current position in the Centres.
- iii. final line - add "Dundee".

With these amendments the minutes were agreed as a true record.

3. MATTERS ARISING

a) Developments with the private sector (3a)

The meeting arranged with the CSA Chairman on 21 May 86 had been postponed to allow all Directors to attend. Miss Corrie was asked to confirm that arrangements were in hand for this meeting to take place on 20 August 1986 following the BTS Sub-committee. *

b) AIDS (3b)

Dr Cash welcomed Dr Foster who had agreed, in the absence of Dr Perry, to present a summary of the present position.

i. Viral contamination of product

The collaborative study between PFC, Professor Weiss and Dr Orr (a member of Dr Peutherer's staff at Edinburgh University) was progressing well. Dr Orr had now returned from London and was continuing work in Edinburgh using high titre material. It was too early to draw conclusions from initial results. In conjunction with Dr Orr's studies the necessary equipment purchases and work at PFC were well underway.

Dr Foster outlined the background to the DHSS request for virus inactivation data in the manufacture of immunoglobulin and reported the current position in PFC. He was unable to say whether or not the PFC would be in a position to meet the DHSS deadline of 1 July and would ask Dr Perry to deal with this question on his return from annual leave.

Dr Cash noted that he had reason to believe commercial manufacturers of immunoglobulins had already submitted the information requested to DHSS.

A review of the stock position in SNBTS Centres of products derived from validated plasma had been undertaken by Dr Perry. The current situation was:

| | |
|--|---|
| Normal IgG (IM) | all products at issue from screened plasma |
| Normal IgG (for use with measles vaccine) | all products issued from screened plasma |
| Specific IgG (IM) | none of the material at issue was derived from screened plasma (it was noted that this topic would be discussed at the forthcoming "supply and demand" meeting of the Co-ordinating Group.) |
| IgG (IV) | the product supplied for hypogammaglobulinaemic patients was derived from screened plasma. Other available product was derived from unscreened plasma. |
| Specific IV IgG | products manufactured from unscreened plasma |

| | |
|--------------------------------|--|
| FVIII concentrate | material currently issued was derived from unscreened plasma but it was anticipated that the position would change fairly soon. |
| FIX | most of the products were now derived from screened plasma. |
| PPSB | stocks of product all derived from unscreened plasma, however, batches derived from screened plasma would shortly be available for issue from PFC and, if appropriate, it might be possible to replace unscreened material with screened material. |
| Normal IgG for diluting anti-D | all products issued from screened plasma |

It was noted that this and other related issues would also be discussed at the Supply and Demand meeting.

No details of testing methods for HIV and hepatitis B had yet been submitted to the Medicines Division of DHSS. Arrangements were currently being made for a special Co-ordinating Group meeting on the topic of quality assurance.

ii. **Tracing recipients of anti-D IgG**

It had been agreed at the meeting of 25 March that Dr Mitchell and Dr Urbaniak would investigate the possibility of undertaking a follow-up study of anti-D recipients to assess HIV status. Initial discussions with local obstetricians and haematologists had emphasised the difficulties involved in such a study and although it was considered theoretically possible it was not a practicable or justifiable proposition.

iii. **Quality Assurance**

As noted at i. above this would be the subject of a special Co-ordinating Group meeting.

An NBTS working party, of which Dr Wagstaff was Chairman, had recently been established to examine QA and Dr Cash had requested Scottish representation. He had now received a letter from Dr Fraser in which it was stated that this question had been referred to the CBLA for consideration because this WP had, in fact, been set up in response to a request from that organisation.

In the event of an unfavourable response from the CBLA the Directors would reconsider the position in terms of the work already undertaken in this area. *

Insofar as NEQAS was concerned it was noted that Dr Peter Phillips of NIBSAC would in future issue materials but that the Chairmanship of the national committee would not be his responsibility. The Directors noted with pleasure Dr Mitchell's recent appointment as NEQAS local adviser in W Scotland.

Dr Forrester was aware of Directors' views on NEQAS and in principle was in agreement with them, however, he now thought that compulsory measures might be more difficult to implement than those conducted on a voluntary basis.

iv. **Counselling**

Dr Cash expressed his gratitude to all colleagues both North and South of the Border, who had contributed to the Workshop on Donor Counselling which had been held in the HQ Unit on 14th May 1986. This had been a very successful and useful exercise.

v. **Current status of antibody positive donations**

Directors reported the current position as follows:

| | |
|-----------|---|
| Aberdeen | Nil |
| Belfast | 1 |
| | +1 ? positive but reason to believe will be confirmed |
| Dundee | 3 |
| Edinburgh | 5 + 3 to be confirmed by WB |
| Glasgow | 2 |
| Inverness | 1 |

vi. **UK discussions on antibody testing**

It was reported that this subject would be discussed at the meeting on quality assurance.

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

It had now been agreed that Dr Cash, along with Dr Perry, would meet trial co-ordinators annually to review progress, the first to be held in autumn 1986. A report would be prepared for the SNBTS Directors.

d) **HLA anti-sera screening (3e)**

This item was deferred in the absence of Dr Brian McClelland.

e) **HIV epidemiological study (3f)**

As agreed at the previous meeting Dr Cash had obtained a copy of the proposed protocol from Dr Wallington and this had been circulated to Directors.

In principle Directors agreed with the objectives of the proposed study but there were a few reservations and it was agreed that Dr Cash should write to Dr Wallington regarding the following: *

i. Directors would wish to see more information on confirmatory testing.

ii. Directors envisaged problems with Phase 2 of the exercise and recommended that epidemiological follow-up must be conducted by local staff.

iii. Concern was expressed regarding confidentiality of donor information.

iv. Directors would wish to have an SNBTS representative.

v. The source of funding to undertake the work involved.

f) **Notes on Transfusion (3g)**

Dr McClelland had written to Dr Fraser with his suggestions for the formation of a team, each of whom would undertake to write specific sections of the revised handbook. It was hoped that a first draft would be ready for submission to DHSS by April 1987, following which Directors' comments would be sought.

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- g) Directed donations and autologous transfusion (3h)
Deferred until Dr Fraser reported back. Meanwhile the Scottish Directors' views (Directors meeting 25/3/86) had been conveyed to their English colleagues.
- h) Unrelated bone marrow donors (3i)
i. Scotland: Directors noted that Drs Gillon and Ghosh hoped to submit a report in September 1986. Dr Robert Crawford's keen interest in the area had been drawn to the attention of Drs Gillon and Ghosh.
ii. UK: Dr Fraser had advised Dr Cash that he and Dr Gunson were due to meet Dr Alison Smithies of DHSS regarding participation in the scheme and the issue of greater BTS control. The views of Scottish Directors on the national nature of the such a programme had been transmitted to Dr Fraser.

- i) Surrogate testing for NANB (3i)
There was increasing evidence that the USA and several European countries were introducing anti-HBc and/or ALT testing of blood donors in an effort to minimise the risks of NANB transmission through blood and blood products. Dr Cash believed that the SNBTS would soon come under pressure from clinicians to introduce testing.

A limited study involving follow up of donors with abnormal liver function tests was about to take place in Edinburgh and Dr Urbaniak had been in touch with a gastroenterologist in Aberdeen who had expressed an interest in investigating post transfusion NANB infection, but he had not yet received a response.

Dr Fraser had advised Dr Cash that he (Dr Fraser) and Dr Marcela Contreras (Edgware Transfusion Centre) were keen to set up a small group to explore the feasibility and practicability of this development and that it was their hope that a Scottish RTC would contribute.

It was agreed to await the outcome of Dr Fraser/Dr Contreras' joint deliberations and to discuss the matter again at that time. *

- j) Funding of fractionation of plasma from Northern Ireland (6)
Dr Cash was pleased to report that appropriate arrangements had now been made for future funding of the fractionation of NI plasma and conveyed, on behalf of the Directors, gratitude for the efforts of Mr Murray and his staff in achieving a satisfactory solution to the problem.
- k) Product liability (8)
Following recent discussions and the attendance of a Legal Office representative at the Co-ordinating Group to advise Directors on the implications of this legislation Dr Cash advised colleagues he had taken up the matter with the General Manager.

The question of whether or not BTS would be liable in terms of paragraph 56 (c) of the EC Directive had been raised, wherein it is stated that the producer has a defence if he can show that "he did not manufacture the product for an economic purpose, nor distribute it in the course of his business." Mr Murray believed that this statement would not exclude BTS from liability in the event of litigation. This and other questions would hopefully be answered when the draft Statutory Instrument became available for comment. It was noted that much depended also on the result of early court cases.

There was considerable anxiety amongst Directors that in the event of possible litigation under this legislation a substantial commitment to record keeping would be required which would have consequential effects on staffing levels and storage facilities. It was clear that product liability would affect the NHS as a whole, as well as many suppliers in the private sector, and central funding was not envisaged.

As had been previously agreed at a Co-ordinating Group meeting Dr Cash would take this matter up at the NBTS Advisory Committee, which included DHSS representation.

4. PURCHASE OF COMMERCIAL BLOOD PRODUCTS 1985-86

The table of purchases by hospital pharmacies prepared by Dr Forrester had been circulated. Dr Cash thanked Dr Forrester for his efforts.

Dr Forrester sought Directors' opinion regarding the possibility of SHHD staff obtaining similar figures each year for submission to SNBTS. There was no doubt that such an exercise was difficult for the BTS and Directors agreed that Departmental colleagues should undertake this task annually; figures collected would be submitted to the June meeting of Directors each year.

Dr Forrester drew attention to the undernoted amendments/comments on the figures supplied.

- a) Ayrshire & Arran Health Board - 47 vials anti-tetanus IgG - this product was, in fact, supplied by BTS and should therefore be deleted.
- b) Lothian Health Board - Activated prothrombin complex (FEIBA) - 1900 units - this figure was wrong. Dr Forrester would let Mr Francis have amended figures when available.
- c) Greater Glasgow Health Board - 133,000 units of FVIII of porcine origin had been purchased for a patient who had developed an allergic reaction to PFC FVIII concentrate.

From a BTS point of view Dr Cash outlined the problems now being encountered consequent upon the heat treatment of FIX products and warned colleagues of the possible increase in commercial purchases of activated Factor IX as a result. Work in this area was ongoing.

There had been significant purchases of albumin in the West, as at the moment, PFC was unable to cope with the demand. However, in view of the imminent increase in production capacity, it was anticipated that in future PFC would be able to meet requirements.

When Dr Perry was in a position to confirm increased production Directors would be asked to consider supplying West Scotland with albumin from the national stock in order to reduce commercial purchases. *

Dr Forrester noted that 74,000 units of FEIBA had been purchased in the NE region but this had not been included in the figures supplied to SHHD. Dr Urbaniak explained that all commercial purchases in the NE were supplied via the BTS and were re-charged to the Health Board. He would send details to Dr Forrester in order that he could update his records. *

If a similar system to that which existed in Aberdeen could be operated nationally BTS would immediately be alerted to developing trends in demand and the difficulties of data collection would be overcome.

Directors welcomed any influence which Dr Forrester could exert in getting agreement that any commercial products which were necessary should be ordered by BTS on behalf of Health Boards. *

5. ENGLAND/WALES DIRECTORS' MEETING

Dr Whitrow's notes of the meeting held on 22nd April 1986 had been circulated. The following points arose:

- a) HTLV-III antibody testing of staff reagent samples
The emphasis of the advisory document to be issued by DHSS would be on the status of reagents. It was likely England/Wales Directors would adopt a similar position to the SNBTS Directors i.e. if staff opt to be tested for reagent samples, all available tests would be carried out.
- b) Guidelines for the use of cell separators in volunteer donors
Dr Urbaniak pointed out that a recommendation to DHSS to reconvene the WP which produced the Code of Practice for Machine Plasmapheresis was required. It was probably necessary to combine this Code of Practice with that prepared for the collection of granulocytes in 1977.
- c) AIDS and AIDS testing
 - i. Publication of Scottish figures
Dr Whitrow had been asked to seek Directors' approval for the publication of Scottish figures of HIV positive donations in the CDSC Bulletin.

There was no objection to such publication provided national figures only were quoted (not regional). It was pointed out that such information should be obtained from Dr J Emslie of CDSU to whom all positive results were relayed. *

ii. Dr Tedder had requested samples of positive sera, in addition to those currently being sent to PHLS. None of the Directors had any objection to supplying samples to Dr Tedder but felt, as a matter of courtesy, Drs Peutherer and Follett should be advised before doing so. It was noted that Directors were due to discuss the collection of "interesting" samples within SNBTS. In the meantime Dr Cash recommended that samples of all non-repeatable positive donations should be kept. *

6. UK REGISTER OF RED CELLS

Dr Mitchell reported no movement in or out of the bank in financial year 1985-86. All donors of rare cells were now HIV tested. There was a potential problem with the supply of packs for freezing as the relevant company had withdrawn from the market. It was hoped that existing stocks would be sufficient to last until such time as another company was able to take over supply, possibly at the end of the year.

7. BLOOD: RECORD KEEPING AND STOCK CONTROL

This referred to the 1984 report by the Central Management Services.

Progress in computerisation continued which would facilitate improved record keeping and stock control.

8. STORES INFORMATION SYSTEM (SIS)

It was noted that at the Supply and Demand meeting on 1st July Directors' approval⁽¹⁾ would be sought for the introduction of a computerised stores information system in 3 Centres (SE, W, PFC) provided this was approved by the SNBTS Computing Project Management Group at its meeting the previous day.

(1) Secretary's note: All Directors attended the meeting of the Computing Project Management Group on 30 June and approval was therefore given at that time to this proposal, obviating the need to introduce this topic on 1 July.

9. EFFICIENCY SAVINGS 1985-86

Dr Cash outlined the background to the Management Committee request for efficiency savings amounting to 1½% of the revenue budget. Considerable anxiety was expressed regarding the effect on individual Regional budgets and the effect on patient-care.

Mr Murray advised Directors that the purpose of the efficiency savings exercise was to redeploy funds in areas where they could be put to more productive use. He stressed that any savings identified this financial year would be returned to BTS in next year's development allocation. In the meantime a letter would shortly be sent to the General Manager of the CSA requesting not only details of savings identified but a note of improvements to service and developments on which such funds would be spent. It was noted that developments such as increased process capacity at PFC meant savings in Health Boards. X

When preparing the SNBTS submission to the General Manager Dr Cash would point out the BTS record of efficiency and its ability to adapt to change and the fact that many efficiency savings could not at this time be quantified. *

10. HBsAg VACCINATION OF STAFF

Dr Mitchell had received requests from Mobile Donor Attendants for a policy ruling on the vaccination of staff against hepatitis B.

It had previously been agreed by Directors to offer vaccination to PFC staff if they wished.

Dr Cash agreed to write to Dr Sharp, Consultant Medical Adviser to the Agency's Occupational Health Service to seek his opinion on this topic. *

11. DATE OF THE NEXT MEETING

Thursday 9 October 1986.

X To be deleted from minutes (see doc 54 on GDB/5/1)
aim
17/7/86