

IN CONFIDENCE

SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE

Minutes of a Directors' Meeting held in the
HQ Unit on 3 March 1987

Present: Dr J D Cash (in the chair)
Miss M Corrie (Secretary)
Dr E Brookes
Dr D B L McClelland
Dr W M McClelland (Item 3b onwards)
Dr R Mitchell
Dr R J Perry
Dr S J Urbaniak (Items 1 to 4)
Dr W Whitrow
Dr J Forrester, SHHD (Items 1 to 4)

Action

1. INTRODUCTION AND APOLOGIES FOR ABSENCE

Dr Cash advised that Dr Jack Gillon would attend for Items 3b(xii) and 4.

Apologies had been received from Dr Fraser, Dr Gunson, Mr Murray and Mr Francis.

Dr Fraser had submitted written comments.

2. MINUTES OF THE PREVIOUS MEETING

The minutes of the meeting held on 17 December had been circulated. Dr D B L McClelland's name had been omitted from those attending and it was agreed to correct this.

3. MATTERS ARISING FROM THE MINUTES

(a) Developments with the private sector

i. **Substantive agreement:** Each private hospital had received during the month of December 1986 the proposed substantive agreement for discussion with the local Transfusion Director. Comments and requests from the private hospitals had been sent to CSA General Manager who had collated them. Dr Cash had submitted to CSA replies to the questions with a medical component while the General Manager would attend to the others.

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The Directors' Co-ordinating Group would have an annual discussion on relationships with the private sector, based on the meeting(s) which each Director would have with his/her private hospitals under the terms of the agreement. Miss Corrie had consulted the Directors about a procedure to be followed to service the agreement and this would be issued as soon as the agreements were signed.

ii **Handling charges:** It had been noted at the previous meeting that the current arrangements for determining handling charges were unsatisfactory and that Dr Cash was hoping that colleagues in CSA, SHHD and the DHSS would collaborate in effecting an improvement.

Dr Cash had no progress to report but understood that the topic was to be on the agenda of a forthcoming meeting at the SHHD.

iii **Laboratory tests:** It was confirmed that the Directors should have been levying charges for laboratory tests from 5 January 1987. It was noted that West Scotland BTS undertake reference work but not routine crossmatching and that no reference tests had been undertaken since 5 January.

(b) **AIDS**

i **Validation studies of PFC products:** Dr Perry tabled a summary of preliminary results of virus inactivation in factors VIII and IX, albumin and immunoglobulin and answered questions. He confirmed that the data represented more than a single experiment.

Heating for 72 hours at 80°C gave satisfactory results using model vaccinia and SLF viruses. In the same test system vaccinia was inactivated to a satisfactory degree by heating in solution for 10 hours at 60°C (Behringwerke method).

It was noted that a company in the USA had patented the concept of dry heating coagulating factor in 1982 and had reinforced this in 1984 by a continuing patent. It was understood that companies manufacturing factor VIII had not challenged the patent and were presumably paying royalties. It was believed that BPL were being pursued for royalties.

Dr Perry undertook to find out exactly what was happening at BPL and to report back. Dr Cash advised he would alert the General Manager.

RJP
JDC

Dr Perry tabled also data on the effect of pH4/pepsin treatment on immunoglobulin products. It was noted that the presence of immune complexes have a protective effect on virus contaminants.

Dr Perry is investigating this effect with HIV and will submit the results for publication in due course.

RJP

Asked about progress being made with regard to the heat-treatment of immunoglobulin preparations, Dr Perry said that recent freeze-drying developments may provide access to a heat treatment process for IgG products. This research is ongoing.

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ii **Current status of HIV antibody positive donors:** Directors reported the current number of positive donations in their regions. The change from 17 December was as follows:

<u>Centre</u>	<u>17 December</u>	<u>3 March</u>
Inverness	1	1
Aberdeen	nil	nil
Dundee	3	3
Edinburgh	9	10
Glasgow	6	6
Belfast	2	2

iii **Seroconversion of previously ELISA positive, WB negative donors:** Dr Fraser had written that he hoped that the AIDS Advisory Group had considered the UK BTS proposal to reinstate donors who (after 6 months of repeatedly positive ELISA and repeatedly negative WB tests) were eventually ELISA negative. It was noted that the meeting in question (on testing) was a sub-group of the main EAGA.

A recent FDA recommendation to re-enter to the panel donors who were ELISA positive and WB negative twice had been circulated.

Dr McClelland agreed, as a member of the EAGA Subgroup, to explore this matter vigorously. it was concluded that there was an urgent need to clarify terminology.

BMCC

iv **SNBTS Microbiological Validation Group:** Dr Perry agreed to confirm to the chairman of this group that their work on HIV must include documenting each Centre's methodology for determining HIV positivity and negativity in donations.

RJP

It was confirmed that the group was established by the Directors (with a representative from each Centre) to advise the Directors and that they had no executive authority. It was the duty of the Centre representatives to ensure that, in considering problems, they provided solutions that were realistic to implement in Transfusion Centres.

v **Donor self-exclusion literature/DHSS AIDS leaflet:** It had been hoped that the NBTS Directors' meeting on 21 January would discuss the possible formation of a joint NBTS/SNBTS group to advise the DHSS on the content of future messages to donors, with the aim of achieving uniformity between the NBTS and the SNBTS. Dr Cash advised that this proposal did not have the support of DHSS.

Dr Fraser had reported (by letter) that the Regional Transfusion Directors in England and Wales were content that the SNBTS should go ahead with their own study.

* Dr Cash confirmed that the Scottish study in question was the subject of discussions with Professor Douglas Leathar (Department of Marketing Strathclyde University) and it had been agreed Professor Leathar would submit proposals to Dr Cash who would consult the Scottish Directors about them.

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Action

vi **HIV epidemiological study:** Dr Fraser had written that Dr Wallington had now finalised the study. It had been modified to the extent that the epidemiological study on household contacts of recipients of possibly infected blood would probably not now go ahead. For that reason Dr Fraser and Dr Wallington did not feel that Ethical Committee approval was needed.

Dr Wallington would send full details of the study to Dr Cash for distribution to the Scottish Directors.

vii **Donor attendance figures:** It had been agreed at the last meeting to include on the agenda every six months a review of donor attendance figures. A graph covering fiscal years 1983-1987 inclusive (the latter projected) was tabled.

Miss Corrie would ensure that an update would be circulated for the June and December meeting and would include the raw data as well as graphs.

MC

viii **Dr Gunson's studies:** Dr Gunson was undertaking two studies, namely

- a. one year's testing in RTCs
- b. the composition of donor panels

Scottish Directors confirmed they had all submitted the information sought by Dr Gunson.

ix **HTLV-I and HTLV-II:** There had been discussion at the English/Welsh Directors' meeting on 21 January on the emergence of two new strains of HIV virus. Dr Tedder and Dr Mortimer were seeking samples from two categories of people, namely those who had been in West Africa and people of West Indian origin on existing donor panels.

(c) Notes on Transfusion

Dr McClelland (editor of the revision of Notes on Transfusion) said that he hoped to produce a draft to the Directors by the summer of 1987.

BMCC

(d) Directed donations and autologous transfusion

i **NBTS developments:** It had been agreed at the NBTS Directors' meeting on 21 January that Dr Lee (RTD, Lancaster) should convene a group of three transfusion directors, three haematologists, an anaesthetist, a surgeon and possibly an obstetrician to produce guidelines for autologous transfusion for England and Wales.

ii **SNBTS developments:** Dr Cash had asked Dr McClelland to examine the possibility of an SNBTS pilot study which would be undertaken in the Edinburgh Transfusion Centre. The object would be to study the organisation, practicability and cost.

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It was noted in the discussion that haematologists in Glasgow had had a series of meetings on autologous transfusion, with Dr Mitchell in attendance, with a view to making representations to the GGHB. It was agreed that the SNBTS should be actively and directly involved in this potential development.

The Directors agreed the following:

Dr McClelland to submit his proposal in time for consideration at a Special Co-ordinating Group meeting to be held on 1 April. It would be decided then whether the Edinburgh Centre would undertake the study on behalf of the SNBTS or if one (or more than one) other Centre should do so.

BMcC

Dr Mitchell to obtain (from the Secretary of the West of Scotland Haematologists' Group) a protocol which it was understood they intended to submit to the Greater Glasgow Health Board.

RM

iii American Red Cross: Directors noted an extract from the American Red Cross Blood Services Bulletin of November 1986 in which the Associate Vice President for Medical Operations of the Red Cross had said that the latter "should be an advocate for autologous blood programmes, offering pre-surgical blood collections and promoting intra-operative salvage whenever feasible".

iv Private autologous blood bank: Directors noted correspondence (which had been circulated) between Dr Cash and Mr Morison SHHD in October 1984 and a further letter from Dr Cash of 28 January 1987, this following the opening of the private autologous bank in Gloucester. The Directors reaffirmed their support for the current efforts being made to oppose the development of non-NHS blood collection agencies in the UK.

Dr Cash would produce for the BTS Sub-Committee of the CSA a document for submission to the SHHD. He would copy it to Scottish Health Board Chairmen.

JDC

(e) Unrelated bone marrow donation

i UK: It was noted that the main working group would meet in April. The sub-group on the donor panel (chairman Dr Gillon) had met in Edinburgh on 17 February and the one chaired by Dr Bradley on matching was due to meet at the end of March.

ii SNBTS: It was noted that Dr Gillon's Scottish group continued to meet.

(f) Surrogate testing for NANB

The UK Working Party on Transfusion-Associated Hepatitis had been reconvened to pursue the issue of implementing surrogate testing for NANB. A proposal for a study which would include the Glasgow and Edinburgh Transfusion Centres had been modified and no Scottish Centre was now being asked to participate.

Action

It was noted that some commercial plasma collectors and non-profit blood collectors in the US had begun surrogate testing in 1987 and that in Britain the Haemophilia Society may adopt a position which put pressure on BPL to ensure surrogate testing was introduced.

The Directors discussed the options open to Scotland and agreed the following:

To recommend to the SHHD that surrogate testing for NANB should be implemented with effect from 1 April 1988 as a national development requiring strictly new funding. Each Director should let Dr Cash know what funds would be required in his/her region, assuming that both core testing and ALT would be undertaken in the Transfusion Centres. It was noted that research was being undertaken into a combined core/surface antigen test.

RTDs

JNF

It was agreed to discuss at a Co-ordinating Group meeting whether the BTS should be doing ALT testing now on the normal population to ascertain normal levels at various ages since this was not information available to clinical chemists.

MC

(g) Product liability

i SNBTS: Dr Cash reported that the General Manager was arranging to meet the Chief Pharmacist, SHHD (the officer responsible at SHHD for product liability). Dr Cash was not certain if he would be invited.

ii NBTS: Dr Fraser had not reported on this matter which was not in the minutes of the English/Welsh Directors' meeting either. Miss Corrie agreed to contact Dr Fraser.

MC

(h) NIBSC/UK Liaison Group

The first informal discussions on closer links with NIBSC took place on 19 January 1987. A note by Dr Cash had been circulated. The remit of the group would be to draw up guidelines for the manufacture of biologicals used in transfusion medicine. The following three working parties had been established:

- i. Therapeutic products manufactured at RTCs
- ii. Therapeutic products manufactured at fractionation centres
- iii. Diagnostic reagents for immuno-haematology.

(i) SNBTS clinical trials

i Co-ordinators' meeting: As agreed at the previous meeting Dr Perry had circulated to the Directors a report of the recent meeting between clinical trial co-ordinators. This was noted.

ii Proposed "teach-in" (clinical trials): Dr Perry reported that the purpose was to invite someone from the registration department of ICI and possibly Dr Rottblatt of DHSS to an informal discussion on the system for clinical trial licensing. The date is 15 May 1987.

Action

iii **Product licences:** Dr Cash reported on a meeting which he had attended with Dr Perry, Dr Forrester, Dr McIntyre and the Chief Pharmacist at the SHHD. They have been informed that Crown Immunity applied only to crown institutions which did not take out product licences. It had been agreed that if Crown Immunity was to be maintained then a substitute registration procedure which was essentially operationally identical to current practice would be required and that this might extend to RTC products.

Dr Cash would report again.

JDC

iv **Compensation associated with adverse reactions in clinical trials and healthy volunteer studies:** It was noted that the current provisions were exceedingly narrow. Miss Corrie was working with CSA Secretary, Mr Mutch, on a proposal for extension and improvement. Miss Corrie would report to the next meeting.

MC

(j) NBTS anti-D plasma supply

Dr Cash had informed the NBTS Directors at their meeting on 21 January that if a formal request for assistance was received the SNBTS was in a position to be of assistance.

In addition Dr Perry had offered to the Director of BPL and Dr Fraser some surplus anti-tetanus (IV) which may outdate if not taken up by NBTS.

Directors agreed to request Dr Fraser to provide an explanation as to why the SNBTS had not been asked by the NBTS to give assistance.

JDC

(k) CBLA/CSA agreement: monoclonal antibody Rh(D) cell lines

Dr Perry reported that he had been told by the CBLA that he would probably now receive only the original cell lines and would not get access to the two subsequent cell lines which the CBLA were reported to be circulating to English Transfusion Centres for evaluation.

(l) NEQAS

i **Advisory panel for haematology:** Dr Fraser reported having written to Professor Waters that the unanimous view of the Transfusion Directors in the UK was that the BBTS should be asked to nominate a representative for the main NEQAS Haematology Panel.

ii **Cancellation of NEQAS/Blood Group Serology Programme:** Dr Fraser had written that the programme had been cancelled for the first three months of 1987 and that he was in discussion with the DHSS who were confident that the programme would commence in April. Dr Fraser did not share their confidence.

The Scottish West and South East Regions had organised local programmes and North, North East and East were recommended to participate in the one in the West. Dr Mitchell confirmed he could accommodate them.

Action

The Scottish Directors recorded their regret that the NEQAS scheme had been abandoned and that not all the former tasks of the BGRL had been continued. It was agreed to review the matter in the future as it may be necessary for the SNBTS to take steps to ensure adequate standards are maintained in SHS laboratories.

4. GUIDELINES FOR EMERGENCY COVER AT NURSING HOMES APPROVED FOR ABORTION BY THE SECRETARY OF STATE

It was noted that nursing homes approved for abortion in Scotland required to have certain blood products available immediately at the nursing home and others available immediately or within 15 minutes of requirement. This second category was 2 units of O Rh negative blood and (for special risk cases) 2 units of crossmatched blood held at the nursing home, hospital blood bank or private laboratory.

Dr Forrester had suggested that the Directors should either confirm their satisfaction with the guidelines or initiate a draft revision for the consideration of the SHHHD. (This followed a query from a nursing home in Stirling which was unable to get its licence renewed because Stirling Royal Infirmary were unable/unwilling to hold the necessary blood for them).

It was agreed that Dr Brookes would draft new guidelines (to include anti-D immunoglobulin) for discussion with the Scottish Directors. Dr Brookes would send a first draft to the Directors, receive their comments and bring a revision to a future Co-ordinating Group meeting.

EB

5. NBTS DIRECTORS' MEETING

Notes prepared by Dr Whitrow had been circulated and the official minutes had now been received. Dr Whitrow answered questions and the following were the main points discussed:

(a) HIV antigen testing of anti-D donations

Dr Richard Tedder was undertaking HIV antigen testing of donations for accreditation for the boosting of volunteers.

After discussion Dr Cash agreed to ask Dr Urbaniak to review the guidelines for the accreditation of cell donors and to make recommendations.

JDC/
SJU

(b) Gloves for donor attendants

It had been agreed that gloves were available for donor attendants and recommended only if they had open lesions.

Dr Mitchell reported having difficulty with donor attendants in his Region who insisted on wearing gloves. They were not issued routinely and his advice to them was that if they had obvious cuts or abrasions they should be undertaking duties other than at the

Action

donor's bedside. Dr McClelland stated that donor team staff in his Region were permitted to wear gloves if they chose.

Miss Corrie was asked to obtain guidelines prepared by NUPE for their members and show these to Dr Mitchell and possibly also the West of Scotland full-time official of NUPE.

MC

6. MINIMUM AGE FOR DONATION

Dr Brookes asked if any colleagues were accepting donors under 18 as her Regional Donor Organiser was interested in such a scheme. The Directors confirmed they were not but would be glad to discuss a recommendation.

It was agreed that Miss Corrie, on behalf of the Directors, should invite the Regional Donor Organisers (with medical advice) to consider the matter and to make a proposal to the Transfusion Directors.

MC

7. DATE OF THE NEXT MEETING

Wednesday 10 June 1987.