

~~IN CONFIDENCE~~

## SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE

Minutes of a Directors' Meeting held in the  
HQ Unit on 6 October 1987

Present: Prof J D Cash (in the chair)  
Miss M Corrie (Secretary)  
Mr J N Francis  
Dr D B L McClelland  
Dr M McClelland  
Dr R Mitchell  
Dr R J Perry  
Dr S J Urbaniak  
Dr W Whitrow (except items 5 and 6)  
Dr J Forrester SHHD  
Mr T MacDonald SHHD  
Dr E Brookes

## 1. INTRODUCTION AND APOLOGIES FOR ABSENCE

Action

Dr Fraser and Dr Gunson had sent apologies. JDC welcomed Mr MacDonald to his first Directors' meeting.

The Directors expressed their sorrow at the recent death of Dr Charles Cameron and JDC agreed to write to Mrs Cameron to convey the collective sympathy of the Directors.

## 2. MINUTES OF THE MEETING HELD ON 10 JUNE

These had been circulated. The following amendments were agreed:

- a. Dr Brian McClelland had been absent during items 2bxi to 3gi inclusive.
- b. A sentence in the minute concerning viral inactivation in PFC products should read "Intramuscular lg6 spiked with live HIV virus showed inactivation of 3-4 logs during storage over 4 weeks."

## 3. MATTERS ARISING

a. Developments with the Private Sector (3a)

i **Agreements:** It was noted that all the Scottish private hospitals receiving blood and products had signed the substantive agreement and that a procedure for maintaining the agreements had been circulated to the Directors.

ii **Handling Charges:** the CSA's General Manager had approved 1 October each year as a common date for revising products and laboratory handling charges. Discussions were to take place on the possibility of a list of PFC product handling charges specific to Scotland, since the CBLA were unable to guarantee to adhere to the UK consolidated system which had been suggested by SNBTS Directors. JDC advised he was due to attend a meeting in SHHD on this topic in the near future.

iii **Monitoring relationships with the private hospitals:** the Directors had agreed (at their Co-ordinating Group meeting on 18 August 1987) to report briefly at the February Co-ordinating Group each year.

Action

b. AIDS (3b)

i **Dry heat treatment of Factor VIII:** the status of the patent claimed by the Sinai Medical Centre was still unclear but PFC had reported their method at the 1987 conference of the International Society of Thrombosis and Haemostasis and there had been no approach by the Sinai Medical Centre. Dr Perry undertook to investigate further.

RJP

ii **Viral inactivation in immunoglobulin products:** Dr Perry reported that a summary of the work to date had been accepted for publication in Vox Sanguinis. The work which the University of Edinburgh were undertaking was due to finish in March 1988. He explained that the viability of the PFC depended on these studies which must be allowed to continue. Dr Forrester explained that the matter was with CSA's General Manager for a decision.

Dr Perry had said at the previous meeting that he was considering heat treating intramuscular immunoglobulin. He reported that he was deciding what priority to attach to this. It was noted that new data were to be published soon which inferred that some I.V. immunoglobulin products had transmitted viruses. The pharmaceutical companies were expected to be pharmaceutical marketing dry-heat-treated immunoglobulin products soon. Dr Brian McClelland agreed to send Dr Forrester a pre-publication copy in confidence of the above data. Dr Perry would circulate to the Directors a paper due for publication in the Journal of Infection.

BMcC

RJP

iii **HIV antibody in first time and repeat donors:** JDC asked those Directors who had not done so to respond to his request for data on the incidence of HIV antibody positivity for first time and repeat donors respectively, 'first time' donors to include former donors who had not attended for four years.

iv **Current status of HIV antibody positive donors:** the following position was reported:

(previously)

North	2	(1)
North East	0	(0)
East	4	(3)
South East	12	(11)
West	8	(7)
Northern Ireland	3	(3)

v **Donor self-exclusion criteria:** it was noted that the Directors had reviewed the current criteria (Co-ordinating Group 18 August) and decided to leave them unchanged till February 1988 when they would consider them again with a view to revision from 1 May 1988.

Professor Douglas Leather (Dept of Marketing, Strathclyde University) was about to commence the study of effectiveness of the BTS publicity, which the Directors had commissioned.

Action

vi **Dr Gunson's studies:** Dr Gunson's letter of 9 September to Miss Corrie had been circulated. The monthly monitoring of anti-HIV testing of blood donors was up-to-date for July and all Regional Directors were receiving monthly reports from Miss V I Rawlinson. Monitoring the accuracy of blood donor screening was being conducted by Mrs Janet Mortimer of the PHLS, who had circulated an interim report on the first year's work to the English Transfusion Directors: Miss Corrie to check if Mrs Mortimer had sent it to the Scottish Directors. The MRC survey of the blood donor population would be completed before the end of 1987.

MC

vii **HIV 2:** In his letter of 31 July to English Directors (copy circulated) Dr Gunson had outlined the procedure for submitting donor samples. Some had now been sent from Scotland. A further report would be given at the next meeting.

MC

viii **Taylor Report:** CSA General Manager had written to the SHHD that the SNBTS did not wish at risk, worried well or HIV ab positive individuals to be referred to the SNBTS counselling service (as the Report had suggested).

Miss Corrie agreed to find out what the published version of the report contained. If the suggestion was still there JDC would ask Mr MacDonald to explain the position to Health Board General Managers.

MC

JDC

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

Dr Brian McClelland reported that 14 of the 16 authors to this UK publication had submitted their contributions, which he was editing. The standard was excellent and he hoped to have a draft towards the end of November.

BMCC

d. Autologous transfusion (3d) and directed donations

i **UK developments:** Dr Gunson's letter of 29 September to Miss Corrie was tabled. This described progress towards harmonising the NBTS and SNBTS guidelines, which had been referred to the BCSH Task Force on Blood Transfusion. When the latter had prepared a document they would submit it to the interested groups, including the Scottish Directors.

MC

ii **SNBTS:** Dr McClelland's study with a gynaecology unit would continue till the end of 1988. So far a very small proportion of the patients had required transfusion. He hoped to extend the study to an orthopaedic unit, since the transfusion rate in certain orthopaedic procedures was high.

No autologous transfusions had taken place in the Inverness, Aberdeen or Dundee Centres.

The Glasgow haematologists intended to report to the Greater Glasgow Health Board that autologous transfusion was not cost effective. They were reporting similarly to the SSAG.

Action

Miss Corrie agreed to ask Dr Gillon for a report from the BMA/BTS forum on which he was the Scottish representative.

MC

It was confirmed that autologous transfusion would always be considered for patients who insisted, even if the Scottish Service did not offer it more generally, because the Directors were unhappy about the alternative, i.e. NHS patients receiving autologous blood from private banks where BTS standards might not be maintained and the inevitable difficulties might arise with regard to patient/donation identification.

iii Directed donations: these were not encouraged generally, but it was noted there was an immunological basis for donations from blood relatives in some cases (e.g. in kidney transplantation and mother-to-baby cases).

e. Unrelated bone marrow donations (see)

i British Bone Marrow Donor Appeal: this appeal had been made public at the end of August and five NBTS Transfusion Centres were co-operating in it. The Scottish Directors had decided not to participate until the UK Working Group had reported.

ii UK Working Group: the note of the third meeting (held on 21 August 1987) was tabled together with a letter which Dr Ian Fraser had sent to JDC. The Directors agreed that Dr Gillon and Dr Yap should represent the SNBTS on an Executive Register Group. They also agreed that Dr Fraser should be invited to chair the Group.

JDC

Dr Gillon's sub-group had prepared donor enrolment literature. Each Scottish Director had seen this and Dr Fraser sought their views about the stage at which a donor would be told, if his/her marrow was to be for a private patient. The Directors agreed that a donor should be told at the point at which he or she was selected to give marrow to a particular patient. Scottish Directors were also asked what they thought about asking donors if they would be willing to go abroad to donate marrow. They agreed that this should be done only very exceptionally and that effort should be put into developing techniques for storage and transport of marrow.

JDC agreed to convey the above recommendations to Dr Fraser with a copy to Dr Forrester.

JDC

The RDOs should see the donor information literature at the appropriate time.

MC

iii European registry: a paper by Dr Michael Jeannet (Geneva) had been circulated with a covering letter from Dr Ben Bradley. Dr Fraser would ask the Executive Committee to consider this paper.

iv UKTS DNA-RFLP typing services: a paper by Dr Jeff Bidwell had been circulated. This would be considered by the Executive Group.

Actio

f. Surrogate testing for NANB (3d)

It was noted that the SNBTS/NIBTS Microbiological Validation Group chaired by Dr Cuthbertson of the PFC were due to make a proposal to the Directors concerning ALT and anti-core testing.

g. Product liability/Product licensing (3g)

The section of the Consumer Protection Act which included Product liability was due to come into force on 1 March 1988.

i SNBTS The Directors supported the view expressed by JDC and the CSA General Manager that the latter should advise the SHHD to ensure that all SNBTS products were licensed as soon as possible. There was a suggestion that the Medicines Commission would reactivate licenses 'as of right.'

It was noted that the prescriber of an unlicensed product would share the risk, which reinforced the need to licence BTS products and reduce the likelihood of prescribers buying licensed commercial products instead.

ii NBTS: the English/Welsh Directors were due to discuss the matter at their meeting on 7 October.

h. SNBTS clinical trials (3j)

i 'Teach-in:' Dr Perry reported that he had arranged a seminar at the PFC on the afternoon of Monday 30 November and would be circulating details soon.

RJP

ii Forward planning: JDC and Dr Perry would be proposing to the Directors that part of the development funds for national clinical trials should be committed to a post of National Clinical Trials Co-ordinator. He would circulate a draft job description for consideration.

JDC

i. CBLA/CSA Monoclonal antibody RhD cell-lines

Dr Perry reported that he had now reached agreement with CBLA. Members of his staff would collect the cell-lines from Bristol later in October.

Off agenda.

MC

j. NEQAS (3m)Action

It was reported that the lapsed NEQAS blood group serology programme would recommence in January 1988 under the aegis of NISBC.

Meanwhile the interim Scottish scheme based on BTS Law had proceeded, and 47 out of a possible 49 laboratories had submitted a return. The Directors agreed that Dr Mitchell should report the results to the head of each laboratory.

RM

k. Guidelines for emergency cover of nursing homes approved for abortion (3n)

Dr Brookes (who was preparing a further draft) sought guidance as to whether she could include the need for nursing homes to have appropriate blood storage refrigerators, since the Nursing Homes Act did not require this. The Directors agreed she could.

EB

l. Minimum age for donation (3o)

Miss Corrie reported that the RDOs (with Dr Brookes as medical adviser), has considered the suggestion made at the March Directors meeting to reduce the minimum age for donation. She reported that the RDOs were unable to make a recommendation for reduction, on medical practical and legal grounds, as follows:-

i **Medical:** Dr Brookes (who had consulted paediatricians) had advised not reducing below 17 years 9 months, since not all youngsters had stopped growing before 18.

ii **Practical:** Based on Dr Brooke's advice the RDOs considered it would be very difficult to cope with a minimum age which was not a discrete year.

iii **Legal:** the minimum age of consent to medical procedures for the benefit of the individual in Scotland was 16. The CSA Legal Adviser had informed Miss Corrie that the age of consent to a medical procedure for the benefit of a third party had not yet been positively established.

The Scottish Law Commission were known to be recommending the lowering of the age of consent in Scotland to 16. Miss Corrie was asked to pursue with the Commission for consent for blood donation to be included and Dr Brookes would reconsider the medical issue with other clinical colleagues.

MC

EB

The Directors agreed also to consider increasing the maximum age (currently 65) and JDC would ask Dr Inskip (Consultant, Glasgow Donor Centre) to look into this.

JDC

m. Commercial blood products (6)

Actior

i Purchases in the year to 31 March 1987: a finalised table had been circulated. It was noted that of the sum of £362,475 spent in the year, 58% had been on FEIBA (which PFC did not produce). The spend on albumin was unlikely to be repeated.

ii Usage of products in Glasgow Hospitals: JDC would report on a future occasion.

JDC

n. PFC products for FVII<sup>a</sup> patients with inhibitors

Dr Perry had undertaken to consider developing a PFC product for patients who were currently receiving FEIBA. He said that it had been reported at the 1987 meeting of the 15th that stimulating immunotolerance, rather than a product, was the way forward.

However Dr Peter Foster of PFC had prepared a paper concerning products, which Dr Perry would circulate to the Directors for discussion. It was unlikely there would be a PFC product in less than 12 months.

RJP

o. Glydebank Hospital

JDC tabled a letter from Mrs N S Munro (Assistant Secretary, SHHD) dated 6 October which conveyed the Secretary of State's approval to grant authorisation to Health Care International, Inc (HCI) to construct a 260 bed hospital at Glydebank. The basis of blood supply was to be a maximum (in the first year of operation) of 7,500 units of whole blood and 2000 units of FFP. HCI would have to meet any remaining requirements from predeposit by patients and donations from person volunteering blood on their behalf (who would not receive any payment).

A press statement by CPA chairman was tabled and the Directors agreed a statement in support of the chairman's, to be issued from the HQ Unit as the sole statement to the press.

JDC

JDC agreed to make it clear to the SHHD through CSA that the 7,500 units would be predominantly red cell concentrates and group O. He would also discuss with the General Manager how best to develop a professional relationship with HCI and would make a recommendation to the Directors.

JDC

JDC

4. NBTS DIRECTORS' MEETING 15 JULY

Dr Whitrow's notes on the meeting had been circulated and were noted. The Directors would discuss Prof Whitfield's study of anti-D prophylaxis at their Co-ordinating Group meeting in November.

MC

Miss Corrie undertook to resolve, as a matter of priority, any remaining problems over HGV drivers' hours under the EEC rules.

MC

Dr Whitrow would send the official minutes to the other Directors.

WW

**5. PROVISION OF RED CELLS, PLASMA AND SERUM TO COMMERCIAL COMPANIES****Action**

Some Directors had received requests from companies to supply them with cells, plasma and serum for internal QA purposes and /or sale, in the latter case sometimes from international companies indirectly through small local companies.

It was agreed that the existing SNBTS guidelines covered this situation adequately provided it was appropriately co-ordinated. It was noted that the CSA's Commercial Interface Steering Group (CISG) must investigate companies before the Agency entered into contracts with them. JDC undertook to remind the General Manager of this.

JDC

**6. WELLCOME HIV Ab MONOCLONAL KIT**

At their Co-ordinating Group meeting on 18 August the Directors had asked the SNBTS/NI Microbiological Validation Group to consider W Scotland's evaluation report of this kit and advise the Directors on any further evaluation which might be needed to assess its suitability for all the Scottish Transfusion Centres and Belfast. The recommendations of the Validation Group were contained in the minutes of a meeting which they had held on 17 September and were tabled. They recommended the Abbott Kit, also (if all the reproductibility data was acceptable) the Wellcome one. They could not recommend Du Pont, largely because of low sensitivity and a very high coefficient of variation on repeat testing.

The Directors accepted the advice of the Microbiological Validation Group about the acceptability of the Abbott Kit and (subject to satisfactory data on reproductibility) the Wellcome one. Miss Corrie would ensure that the data were notified to the Centres as soon as they were available. Dr Perry agreed to circulate a summary of the validation date.

MC

RJP

**7. DATE OF THE NEXT MEETING**

Tuesday 8 December 1987.