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Action

SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE

Minutes of a Directors Meeting held in the HQ Unit on 8 December 1987

Present:
Prof J D Cash (in the Chair)
Miss M Corrie (Secretary)
Dr E Brookes
Dr D B L McClelland (3biii/onwards)
Dr M McClelland
Dr R Mitchell (part Item 2 onwards)
Dr R J Perry
Dr S J Urbaniak
Dr W Whitrow
Dr I D Fraser, Bristol
Dr J M Forrester, SHHD
Mr T Macdonald, SHHD

1. **INTRODUCTION AND APOLOGIES FOR ABSENCE**

There were apologies from Mr Francis and Dr Gunson.

2. **MINUTES OF THE PREVIOUS MEETING**

The minutes of the meeting held on 6 October 1987 had been circulated. The comments and requested amendments are attached at Annex A together with a note of the decisions taken.

3. **MATTERS ARISING**

a) Developments with the Private Sector

Handling charges: a note had been circulated of a meeting held in the SHHD on 14 October to consider ways of increasing the Scottish input to the setting of handling charges. The following had been agreed:

RTC Products: there would be Scottish input to UK handling charges by April 1988.

PFC: the existing handling charges would be increased for inflation and followed later by charges based on the Lapsley/Mitchell study.

JDC confirmed that there would be ample opportunity to discuss the Lapsley/Mitchell study at the appropriate time. JDC

b) AIDS — Action

i **Dry heat treatment/patent:** Dr Perry reported that the Sinai Medical Centre appeared to have withdrawn their claims. Stanford University had filed an application which appeared to be out of time and the belief at CBLA was that there was no longer a problem. **Dr Perry to bring the matter up again if necessary. Otherwise, off Agenda.** — MC

ii **Release of untested plasma for fractionation:** there had been a meeting at the SHHD, the recommendations from which had been as follows:

" • that blood products already pasteurised as a final stage, and stock destined for such products, can be safely utilised; and

• that hyperimmune intermediates and products can safely be utilised; to discard them removes certain remote risks at the price of others. But

• in the interest of the greatest practicable safety, hyperimmune plasma not yet processed (e.g. anti-D, anti-measles) should be retrospectively accredited and used where accreditation is complete, but discarded where it is not."

It was explained that a recommendation was being made now to the Minister. **Meanwhile Dr Perry would issue to the Transfusion Centres the reference numbers of those packs for each specificity which were not accredited.** This would enable the Centres to commence identifying donors. Those donors who were currently HIV negative could be assumed to have been negative previously. — RJP/ RTDs

iii **Heat treatment/AIDS validation studies, PFC:** it was believed that the problems would soon be resolved, the bulk of the work being done at the PFC, the large-scale culturing elsewhere.

iv **HIV antibody in first-time and repeat donors:** a Table had been circulated of the numbers of confirmed HIV antibody positive donors in the Scottish Transfusion Centres in the year ended 31 March 1986/7 shown against the number of donations tested. The positivity in new donors was substantially higher than in repeat donors and the data reflected the incidence of AIDS in the regions.

The Directors agreed there was a need to consider improving the performance of alternative testing facilities in Edinburgh & Glasgow and JDC undertook to contact the Chief Medical Officer on the Directors behalf that the CMO should consider such testing sites (which should be well advertised). Dr Fraser reported the apparent success of a high-profile publicity campaign in Bristol and Plymouth allied to centrally-sited testing centres with extended opening hours. — JDC

Dr Brian McClelland would circulate to the other Directors the data which Dr Jack Gillon had presented at Scotblood in 1987. The Scottish Directors to discuss the matter again once Dr Gillon's data was available. — Action: BMcC MC

v **Dr Gunson's studies:** A paper had been circulated.

All Scottish Centres had participated in the study of anti-HIV testing. The NBTS Directors had not so far considered the proposals which had emerged from the study. It was noted that the Scottish Microbiological Validation Group were due to report soon to the Scottish Directors on the performance of Scottish Transfusion Centres. It was noted also that PHLS were receiving HIV positive donations from the Scottish Centres.

All Scottish Centres had contributed also to the study of the donor population. Dr John Emslie of the CDSU Scotland had notified Prof Cash that the Unit were about to initiate a study of the Scottish donor population and Prof Cash was arranging for him to meet the Scottish Directors. — JDC

vi **Current status of confirmed HIV antibody positive donors:** the following numbers were reported:

North	2	South East	12
North East	0	West	9
East	4	Northern Ireland	3

vii **HIV 2:** There was nothing further to report since the meeting at which it was noted that the Wellcozyme test appeared to be picking up HIV 2 positives.

c) **Donor attendance figures**

A graph was tabled of attendances in the years to 31 March 1984-1988 (the latter based on the first seven months of the year). Attendances in November 1987 were slightly higher than in October for the SNBTS as a whole but there were Regional variations.

d) **Notes on Transfusion/Transfusion Medical Handbook**

Dr Brian McClelland reported that the position was still as it had been at the previous meeting, namely that he was awaiting two final contributions.

e) **BMA/BTS Forum on AIDS**

This was previously known as 'Autologous transfusion and directed donations.'

It was reported that a UK forum of BTS and BMA on AIDS had been set up, the Scottish Office of the BMA making the arrangements. SNBTS members were Dr Perry and Dr Gillon. The Scottish BMA were to prepare a paper on matters such as autologous transfusion, research and hospital transfusion. Dr Gillon had prepared a discussion paper on autologous transfusion and Dr Perry one on research. Neither had been discussed because of a meeting being cancelled. Action

Dr Perry agreed to circulate both papers to the Directors. RJP

JDC to write to the Scottish secretary of the BMA to find out, and influence, how the information was to be presented, to ensure that the BMA consulted formally with the SNBTS and the Scottish Directors. JDC

Dr Perry would keep the Directors informed of developments within the forum. RJP

f) Unrelated bone-marrow transplantation

Dr Fraser reported that the Executive Group considering the donor register had met on 10 December. They considered how to expand the panel and whether to include platelet-only donors in a national register. They were also considering recruitment methods, how to relate to the Anthony Nolan panel and whether to link into Europe. There would also be a prospective study of DNA matching.

Funding was being shared by the Regional Transfusion Centres, UK Transplant and the British Bone Marrow Donor Appeal.

The Centres at Belfast, Leeds, South London and Birmingham had been funded by the British Bone Marrow Donor Appeal for typing and two Centres were awaiting funds.

It was noted that difficulties were emerging in relationships with the UKTS.

g) Surrogate testing for NANB

It was noted that the Directors Co-ordinating Group Meeting had decided on 10 November the following:

ALT testing: the SNBTS Microbiological Validation Group to reconsider to what extent it was necessary for every Centre to be involved in evaluating the technology and to report on the matter by 31 March 1988.

Anti-core Testing: it had been agreed not to consider anti-core testing further until the report on ALT testing had been received and discussed by the Scottish Directors.

h) Product liability and product licensing — Action

i **SNBTS:** JDC had suggested that he should meet the Legal Adviser to the Health Service in Scotland and the Chief Pharmaceutical Officer to review the position. It had been agreed at a meeting in SHHD that the SNBTS should apply for manufacturers licences in respect of current products. It was noted that the Chief Pharmaceutical Officer claimed he was the licensing authority for Scotland.

Dr Perry reported that the PFC had a tentative time scale to achieve product licences by the end of 1988.

UK: a meeting was being arranged at the University of Lancaster on 4 and 5 January 1988 to advise the UK Transfusion Services on the application of product liability to the NBTS. There would be representatives from the legal department of the DHSS, from the MDU and the Inspectorate.

It was noted that the liability of prescribers might lead hospital consultants to refuse to use BTS products if they were not licensed.

JDC considered that the General Manager and Management Committee of the CSA would be taking action on manufacturers' licences in a few months time.

i) SNBTS clinical trials

i **"Teach-in:"** this took place on 30 November.

ii **National clinical trials/product surveillance officer:** the CSA General Manager was considering the SNBTS Directors' proposal for this post.

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

Dr Brookes reported that she had received comments only from Dr Mitchell and JDC on her fourth draft. These comments were discussed briefly then **it was remitted to Dr Mitchell, JDC & Dr Brookes to incorporate them as appropriate.** — RM/ JDC/ EB

k) Age limits for blood donation

i **Minimum:** the Scottish Law Commission (whose recommendation about age of consent was to be published shortly) were encouraging the SNBTS to make know their support for the proposals. **Miss Corrie undertook to keep in touch and see that the Directors support was notified.** — MC

ii **Maximum:** Dr Mary Inskip (Consultant, Glasgow Donor Centre) had agreed to investigate the scope for increasing the maximum age limit.

l) PFC products for Factor VIII patients with inhibitors — Action

A meeting had been held in the SNBTS on 26 October to discuss strategy for Factor VIII inhibitor patients and a copy of the meeting report had been circulated.

The meeting was held against the background of a heavy expenditure (£288,000 in 1986/87) on commercial products to treat about 15 patients (the aim of the meeting had to be been to see if the PFC could manufacture an effective and acceptable product. It had been agreed to manufacture a new F IX preparation without additional anti-thrombin III. This would be named 'SNBTS inhibitor product.' Dr Perry expected that the PFC could achieve this by June 1988. Given the small number of patients clinical trials would be difficult to arrange.

Dr Perry, Dr Boulton & Dr Ghosh would visit the Scottish Haemophilia Directors to explain the position and JDC hoped that the SNBTS would reach a greater understanding and measure of co-operation with them. — RJP

m) Clydebank Hospital

It had been considered inappropriate for the SNBTS to make an approach for the time being but it was important to know when the project was likely to begin. **Mr Macdonald would notify JDC as and when he had any information.** — T Macd

4. NBTS DIRECTORS' MEETING 7 OCTOBER 1987

The official minutes of the most recent NBTS Directors meeting had been circulated and the following aspects were discussed:

a) Scientist & MLSO Staffing

Problems in recruiting MLSOs which had originated in the south were now spreading. A group had been established with Dr Fraser in the chair to consider the problem and make recommendations. One proposal they had in mind was a common spine for all scientific employees on the pattern of CBLA. The Association of Clinical Biochemists and the Association of Clinical Pathologists were supportive. It appeared that the PHLS was taking up the same concept.

Dr Fraser's group would include Professor Cash and one Scottish Principal MLSO.

The group would report to the UK Transfusion Directors in due course.

b) Follow-up of HIV antibody positive donors

The English position had been confirmed, namely that the DHSS Legal Department believed it was the duty of the doctor to follow up such donors, even to the extent of visiting the donor's home.

The SNBTS Directors had decided previously not to go so far as to visit such donors. This had been also the view of the Scottish Health Service Legal Adviser. Dr Forrester was happy that the matter had been considered in Scotland.

c) **Performance indicators**

The Royal College of Pathologists had established a Working Party to study performance indicators. NBTS Directors had been asked to submit their views on what the BTS performance indicators should be to Dr Fraser, who would attempt to distill a number of useful indicators from this correspondence. It was noted that no interest in this topic had yet been promulgated by SHHD or the CSA.

d) **Blood bag fault monitoring system**

The scheme had lapsed and Dr Ala (Birmingham) was of the opinion that it should be reactivated in a simpler form in view of product liability.

It was noted that Dr Mitchell had written to Dr Ala (Birmingham) and the Scottish Directors on this subject and the latter would consider it at a forthcoming meeting.

5. **UK BTS HEPATITIS B REGISTER**

A proposal to establish a register of Hbs Ag positive donors had been circulated from the NBTS Directors. Dr John Barbara of Edgware would organise it.

After discussions the SNBTS Directors agreed in principle to support only those parts of the proposal concerning the register of Hbs Ag positive donors, and to do so only on the basis of not identifying donors by name. JDC would notify Dr Barbara.

6. **DATE OF THE NEXT MEETING**

Tuesday 12 April 1988.

ANNEX A

DIRECTORS' MEETING 6 OCTOBER 1987: COMMENTS AND REQUESTED AMENDMENTS

3a. **Developments within the private sector** "The procedure was unacceptable to Dr Mitchell who explained that he would have to conduct individual meetings with individual private hospitals in his region. His normal practice was not to give reports on any hospital within the NHS sector or the private sector and according to the procedure circulated, his reports would be extremely abbreviated in February of next year" (Dr Mitchell).	**Not Accepted**
3b. **AIDS** i. **Viral inactivation in immunoglobulin products:** "The first sentence to read Dr Perry reported that a summary of the work **on intravenous immunoglobulin** to date had been accepted for publication in Vox Sanguinis" (Dr Perry).	**Accepted**
iii. **HIV antibody in first time and repeat donors:** "Dr Mitchell tabled the information and cautioned other Directors about the need to caluclate their figures on the same criteria as those given by Dr Rawlinson and Dr Gunson from Manchester" (Dr Mitchell).	**Accepted**
3d. **Autologous tranfusion** "I think there must be a mistake in the first paragraph. I think at the BTS Sub-Committee meeting Mr Hugh Morison of SHHD suggested that the Edinburgh study should be extended for a reasonable time but certainly not to the end of 1988" (Dr Mitchell).	**Not Accepted**
3e. **Unrelated bone marrow donation** ii. **UK Working Group:** "We agreed only that Dr Gillon and Dr Yap (who are both from the same RTC) would represent the SNBTS on an interim basis until the terms of reference of the Executive Register group were known" (Dr Urbaniak).	**Accepted**
3g. **Product liability/product licences** Insert after the first sentence "Mr Macdonald made the point that, as regards the sections on product liability, crown immunity would not apply. That did not, however, affect the question of crown immunity more generally, including the position on product licences" (Mr Macdonald).	**Accepted**