

file copy.

26

IN CONFIDENCE

SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE

Minutes of a special meeting of the Co-ordinating
Group held in the HQ Unit on 7 February 1984

Present: Dr J D Cash (in the chair)
Dr E Brookes
Dr D B L McClelland
Dr R J Perry
Dr S J Urbaniak
Miss M Corrie (Secretary)
Mr J Davidson
Dr W M McClelland (1 to 3c and 5 to 12)
also attending: Dr B Cuthbertson (3)
Mr A Dickson
Dr P Foster
Mr W Grant
Dr R McIntosh
Dr A Welch

1. INTRODUCTION AND APOLOGIES FOR ABSENCE

Dr Cash welcomed to the meeting Dr Perry in his capacity as acting Director of the PFC for a period of six months commencing 1 January 1984. He also welcomed Mr John Davidson to his first meeting.

Apologies were notified on behalf of Dr Whitrow, who was on leave and Dr Mitchell (who had been forced to turn back by bad road conditions).

It was decided to proceed with the meeting despite Dr Mitchell's absence. On a suggestion from Dr Cash it was agreed to deal first with items 5-12 inclusive followed by items 1-4. These minutes however follow the order of the agenda.

2. MINUTES OF THE PREVIOUS MEETING

The minutes of the special meeting on immunoglobulins held on 23 September 1983 had been circulated and the following amendments which had been proposed were agreed.

- a) Minute 2a (ii), paragraph 2 - replace by "It was agreed that there was a continuing need for the intramuscular administration of immunoglobulin."
- b) Minute 3d, line 6 - replace "would" by "could".

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

3. IMMUNOGLOBULINS

a) Intravenous preparations

i. Trial of PFC product

At the special meeting on immunoglobulins on 23 September 1983 the Co-ordinating Group had agreed that proposals would be received from Directors for trials involving the use of possible small surpluses of intravenous IgG not required for the treatment of hypogammaglobulinaemic

patients. Dr McClelland had circulated such a proposal in his letter of 4 October 1983 and enclosures. He had hoped to speak to these at the meeting on 22 November 1983 of the Co-ordinating Group but had been unable to attend and the matter had been deferred until the present meeting.

Dr McClelland sought his colleagues' approval to make available to SE Scotland BTS a maximum of 2 adult course/year of intravenous immunoglobulin to be used exclusively for the treatment of suitable cases of adult auto immune ITP according to criteria given in a brief protocol (which had been circulated). The purpose of this was not to conduct a formal clinical trial but to attempt to demonstrate whether the PFC immunoglobulin behaved like Sandoglobulin (a commercial intravenous IgG manufactured by Sandoz) which had already been trialed.

It was agreed that there was a need for as much clinical data as possible on the PFC product without detriment to the clinical trial already organised in respect of hypogammaglobulinaemic patients. Dr Perry confirmed that he could provide 500 gm per month for these ITP patients without detriment to any other programme. Dr McClelland explained that the proposal was not for a formal clinical trial but that the product would be issued to appropriate clinicians as required. A definition of ITP would be made and circulated to the other Transfusion Directors who could call on the PFC product for uncontrolled studies in their region.

It was agreed that any full clinical trial would best be conducted in W Scotland BTS.

Progress would be reported at a forthcoming Co-ordinating Group meeting.

ii. Anti CMV Immunoglobulin

Dr Cash explained the following components of this item:-

- (a) Renal Study
- (b) Letter from Dr F H Ala, Director, Birmingham RTC
- (c) Bone marrow transplantation trial
- (d) Other applications

The main points of the discussion were as follows:-

(a) Renal Study

A paper by Dr Yap and Dr Cuthbertson entitled "An update on recent usage and proposals for the future use of CMV immunoglobulin" (January 1984) had been circulated by Dr McClelland under cover of his letter of 25 January 1984. The trial had commenced on 1 October 1983 and there had been a relatively disappointing response so far, only 3 patients having been enrolled.

Dr Cash noted that a trial elsewhere had foundered following the intrusion of a commercial producer and wondered whether this might be a reason for the lack of cases. Dr McClelland agreed to investigate so far as possible.

(b) Letter from Dr Ala

A letter dated 11 January 1984 from Dr F H Ala, Director, Birmingham RTC together with a protocol proposed for his bone marrow transplant trial had been circulated. His proposal was to undertake a trial in bone marrow transplant recipients using CMV immunoglobulin fractionated by the PFC from high titre plasma supplied by Dr Ala's Transfusion Centre.

In discussion it was agreed that if the trial was well organised and managed it would provide useful clinical data to SNBTS. It would be necessary to check whether Dr Ala had the same selection criteria for donors as the SNBTS. It would be necessary also to know exactly how much immunoglobulin would be required. Dr Cash undertook to write to Dr Ala on these lines.

(c) UK bone marrow transplantation programme

The suggestion that the PFC product might be used in Scotland and England in CMV infection following bone marrow transplantation was considered. It was noted that there was only one official marrow transplantation unit in Scotland and that this Centre would not wish to participate. It was agreed to try to establish whether it was possible to get the SNBTS product trialed in this clinical context and Dr Cash agreed to contact Professor H Kay.

(d) Other applications

The proposals for the treatment of neo-nates with pneumonitis was noted with interest. Dr McClelland had neo-natal aliquots of frozen female anti-CMV plasma for anyone who required it.

Dr McClelland was asked, together with Drs Yap and Cuthbertson, to quantify the proposal for an uncontrolled trial of CMV immunoglobulin in diagnosed cases of AIDS with demonstrable CMV infection.

b) Clinical trial of hepatitis A immunoglobulin

Dr McClelland had circulated a paper containing a proposal for a clinical study of HAV immunoglobulin with regard to its efficacy and adverse reactions, the product would be a batch of high titre anti-HAVIG plasma which had already been fractionated by PFC to powder. The Directors welcomed this proposal and asked Dr McClelland to invite PHLs colleagues to provide further details of this proposed study and report back.

It was agreed that a similar study should, if possible, be undertaken in Scotland and Dr Urbaniak undertook to make enquiries in Aberdeen.

c) General developments

The following papers by Dr Perry had been circulated:-

- i. Manufacture of immunoglobulins
- ii. Progress report on studies to improve the yield and quality of anti-D

Dr Perry introduced both documents which were then discussed with himself and his colleagues from PFC. It was noted that PFC were offering to improve the yield of their immunoglobulins and its stability through minor modifications in the chemistry and ultra filtration. Responding to a criticism of the data which had been supplied in the paper on anti-D Dr Perry said that PFC were manufacturing one batch per week each of which could be subjected to yield analysis thus providing substantial data on yield and quality within 2 months.

A suggestion was made that a batch of Scottish anti-D plasma might be sent to BPL to be processed (this would be an interim measure pending a solution to PFC problems and to allow them to complete their study and modifications). Dr McClelland expressed concern about submitting any further donors to boosting in the light of current excessive losses at PFC.

After further discussion it was agreed not to send plasma to BPL meantime. Dr Perry would report the current stock position to Dr Cash and would initiate a series of production runs, using normal (non-immune) plasma to

examine the feasibility and efficacy of the new chemistry. It was agreed that the end product of this exercise could be used for patient care. It was also agreed that pending further information there would be no introduction of ultra filtration in place of freeze drying.

d) Hepatitis B immunoglobulin vial size

A letter dated 15 December 1983 had been received from Dr Morris McClelland in which he had asked whether mini-dose vials could be produced for use in neo-nates. Dr Perry undertook to make a batch (e.g. a 3-year supply) some of which could be offered to BPL. Dr McClelland would ask Dr Polakoff of the PHLS what the uptake in the UK was likely to be in the light of the introduction of new protocols which incorporate the use of vaccines.

4. FACTOR VIII SUPPLY AND DEMAND

Papers from PFC and Dr Cash had been circulated. It was agreed that they should be discussed in detail at the 1984 'Pro Rata' meeting to be held on 2 May.

Dr Perry reported that he envisaged a shortage in storage space for the finished product would develop within the next 6 months and Dr Cash explained that it might be possible to send surplus Factor VIII to the NHS in England and Wales: he would report on this at a later date.

5. ADVISORY PANEL ON DISPOSAL OF SURPLUS BLOOD PRODUCTS

During the deliberations on the above Dr Cash had been asked to try to delineate the type of surplus products which other agencies might wish to receive from the SNBTS. He had circulated a table to the Directors for discussion at the Co-ordinating Group meeting on 22 November. It had been decided at that meeting to defer discussion until more Directors could be present.

The table was discussed and amended and it was noted that an amended copy would be circulated and that the topic would be discussed at the forthcoming BTS Sub-committee meeting.

In response to a request from Dr McClelland Miss Corrie undertook to obtain references which had been quoted at the November meeting of the BTS Sub-committee by a member of the Central Legal Office. These concerned the Secretary of State's ownership of blood taken for the purposes of transfusion.

6. AIDS

Dr McClelland had circulated a report which he had prepared at the request of the Co-ordinating Group. After discussion the following matters were agreed:-

a) UK Working Group

Dr Cash should write to SHHD and to Dr Gunson (to whom Dr McClelland had copied the report) recommending that there should be a single UK Working Group with Scottish representation.

b) Leaflet improvements

Dr McClelland had produced a revised leaflet for potential circulation to all donors. This would be discussed at an ordinary Co-ordinating Group meeting.

*Coord group
7th Feb
1984*

- c) Donor screening studies
The Working Group ((a) above) should be encouraged to mount studies in some of which the SNBTS should play an active part.
- d) SNBTS plasma processing policy
It was agreed to restrict the use of plasma containing high titres of CMV and hepatitis B antibody to the production of immunoglobulin and albumin products and to ensure its exclusion from coagulation factor preparations.
- e) Auto transfusion
The greater use of auto transfusion might be studied in selected Transfusion Centres. Dr Cash would suggest this in his letter to SHHD and Dr Gunson.
- f) Small pool FVIII
It was noted that small pool freeze dried cryoppt for hemophilia therapy may have to be reassessed. Dr Perry said he could manufacture such a product (given the appropriate resources). To be included in Dr Cash's letter.
- g) Anti-D (donor selection and in vitro production)
On donor selection it was agreed to await a paper which Dr Urbaniak and Dr Boulton were preparing. It was noted that work was proceeding in SE and W Scotland directed towards the in vitro production of anti-D.

7. PRIVATE SECTOR: MODEL AGREEMENT

- a) Non-crossmatched blood
b) Crossmatched blood

It was noted that Directors had received copies of the final drafts of both above agreements which had been submitted to CSA Secretary. Dr Cash (who felt they might be unacceptable to the SHHD and DHSS) did not envisage their imminent appearance at the BTS Sub-committee.

In the light of possible problems in regard to levying charges for crossmatched blood Dr Cash had written to CSA Secretary recommending that the SNBTS should not increase its present commitment to crossmatching and grouping blood for the private sector until the ground rules had been established formally (i.e. with CSA and SHHD) especially in connection with charges. It was agreed that an early decision on the matter was important: Dr McClelland in particular was being pressed by BUPA to crossmatch blood for the Murrayfield Hospital in Edinburgh due to open in July 1984.

8. DONATIONS TO THE SERVICE

At the Co-ordinating Group meeting on 7 December it had been remitted to Dr Cash and Miss Corrie to discuss with the Treasurer the manner in which the latter intended to hold on behalf of the SNBTS donations which had been made to the Service. In particular the Co-ordinating Group were concerned that Directors should have ready access to the funds, that they should be tax-free and obtain favourable investment terms.

The Treasurer had been able to confirm that he would seek charitable status for the funds so that tax would not be payable and that he would see that they were invested appropriately from the point of view of income. For the purpose of obtaining charitable status he would require to have a "constitution" in respect of each Transfusion Centre: this would outline the purposes of the fund and the rules governing it.

Miss Corrie undertook to ask the Central Legal Office for a simple form of constitution.

9. IAIN COOK MEMORIAL LECTURE FUND

At the Co-ordinating Group on 22 November 1983 it had been noted that a relative of Dr Iain Cook wished to donate a sum of £1,000 to found an annual lecture to be delivered at Scotblood.

A constitution drafted by Dr Mitchell had been agreed and it had been agreed also that the National Medical Director should arrange to invest the money.

Miss Corrie explained that she had now received a cheque from Ms Felicity Masterton (Dr Cook's daughter) which she had deposited with the Treasurer on the basis of the undertakings which he had made for donations to the Service (item 8 above).

Miss Corrie undertook to look again at the constitution, prepare any draft revision necessary following the last Co-ordinating Group meeting and send it out for comment.

10. SENIOR REGISTRAR ESTABLISHMENT

a) 1984 Projected establishment

Dr Cash tabled the projection table for the 1984 Senior Registrar establishment which had been discussed at the recent annual SR establishment meeting held at SHHD. He had already telephoned and discussed its content to the Directors. The table showed a proposed reduction from the 1983 establishment of 5 to 3 in 1984. The target had been confirmed at the SR meeting at SHHD and Dr Cash had not found it possible to disagree with the conclusion that 3 posts were sufficient.

b) Effecting the reduction

Dr Cash proposed that the 3 posts should be allocated one each to North East, South East and West. This was accepted by those Directors present who had an interest in the matter. The reduced establishment would bring a requirement to take positive action in the case of time expired SRs.

There would be no need to review the Registrar establishment which stood at 4. It was noted that there was a national embargo on the creation of further Registrar and SHOs posts.

11. PROPOSALS FOR ENHANCING SNBTS SCIENTIFIC AND OPERATIONAL MANAGEMENT LIAISON AND INFORMATION EXCHANGE

Since the last meeting of the Co-ordinating Group Dr Cash had circulated for comment a paper which had been then subsequently re-drafted (taking into consideration Directors' views obtained by telephone) and submitted to CSA Secretary for consideration by the BTS Sub-committee.

Dr Cash undertook to send a copy of the revised paper to the members of the Co-ordinating Group.

12. CIRCULATION OF CSA MANAGEMENT COMMITTEE AND SUB-COMMITTEE MINUTES

Miss Corrie explained that Dr Cash received four times a year (after each meeting of the Management Committee) a copy of the minutes of that Management Committee meeting plus the Sub-committees which had taken place in the previous 3 months. She tabled samples of these minutes, explained that she had the General Administrator's authority to circulate them and asked the Directors if they would wish to receive them.

It was agreed that they should be circulated to each Transfusion Director for an experimental period of 6 months.

13. DATE OF THE NEXT MEETING

Thursday 16 February to discuss statistics and the proposed Safety and Adverse Reactions Register.