IN CONFIDENCE

SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE

Minutes of Directors' meeting held in the BTS
BTS Headquarters Unit on Tuesday 13 September 1983

Present: Dr J D Cash (in the chair)
Dr E Brookes
Dr R Mitchell
Dr S J Urbaniak
Mr J G Watt
Dr W Whitrow
Dr A E Bell (SHHD)
Mr J O Wastle (SHHD)
Dr W Wagstaff, Sheffield, items 1 to 6
Dr W M McClellland, Belfast, items 1 to 6
Dr B K Verma (visitor)
Miss M Corrie (Secretary)

1. INTRODUCTION AND APOLOGIES FOR ABSENCE

Apologies were notified from Dr H H Gunson and Dr D B L McClelland.
Dr Cash welcomed Dr Verma to the meeting.

2. MINUTES OF THE PREVIOUS MEETING

The minutes of the meeting held on the 14 June 1983 had been circulated and the following amendments were agreed:
Minute 3d
add the words "because serial coding rather than lot number was not practicable."
Minute 7
delete, in lines 7-9 of this minute the words from "because" to "content."
To the penultimate sentence add the words "for consideration by the Directors."

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

3. MATTERS ARISING FROM THE MINUTES

a) Freeze dried plasma (3a)

It was noted that on 30 August Miss Anne Sutherland (Bangour), Dr John Settle (Wakefield), Dr W Reid (Glasgow) and Mr JH Stevenson (Dundee) had met the Scottish Directors.

It was agreed that there was a need for a trial, that the Scottish Directors' fear that there was no standardised protocol was misplaced and that (after further explanation) it was clear that the proposed randomisation was acceptable. Dr Settle had undertaken to supply a revised protocol while Mr Watt (after discussion with his staff) would recommend a suitable starting date for the trial. It was noted that it would be put to the Ethics Committee of each of the participating units.

b) RTC Quality Assurance programme (3b)

i. Regional QA programme

Dr Cash recalled that Quality Assurance had been a recurring theme during the Medicines Inspector's visits. It was recognised that there were no guidelines on QA in blood products and the Scottish Directors had decided that QA should not be increased excessively, i.e. through staff developments, unless they were in difficulty. It was noted that some Transfusion Centres had taken advantage of staff vacancies to make adjustments and there had been one development proposal in Aberdeen.

As explained at the previous meeting Dr Cash had been collecting information from all the Transfusion Centres on their existing QA and he had tabulated and circulated this information and was awaiting comments. Once these had all been received he would recommend discussion in order to produce a working basis for QA in blood products.

ii. "Standards For The Collection....."

As agreed at the previous meeting Dr Cash had conveyed to the appropriate office in the SHHD the Directors' willingness to assist in any rewriting of the above which might be envisaged. He had received no acknowledgement. It was noted that this publication was prepared by the Licensing Authority not the Medicines Inspectorate. Dr Wagstaff reported he had discussed the topic with relevant officers in the DHSS. They were unaware of any plan to rewrite it but acknowledged that if there was it would be appropriate for the Transfusion Service to be involved.

iii. Guide to Good Manufacturing Practice

It was noted that the third edition of the above was now on sale from the Government Bookshop.

iv. Medicines Inspectorate Action Group

There was some discussion on the reaction of the above group to the Directors' responses to the Medicines Inspector reports. These reactions had been circulated to the Directors and concern was expressed at the limited nature of the Action Group's response. Mr Wastleconfirmed that what the Directors had received was indeed the complete deliberations of the Action Group. They appeared to have concentrated solely on the points they had raised in their initial report with the consequence that the development proposals which had been submitted to the SHHD were wider than the comments subsequently received from the Action Group. Mr Wastle said that the SHHD reaction on the proposals was due very shortly.

c) AIDS (4)

It was noted that since the last meeting the UK leaflet had been produced and, the Ministers of Health having made statements on the matter, the leaflets were being distributed. The method of distribution had been left to the Directors who reported as follows:

North:
on display with other publicity leaflets at donor sessions and in plasmapheresis rooms. There had been no reaction to them.

North East:
available at all mobile and fixed site sessions. Very little reaction.

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East:
on display at the clerking desk. Anyone requesting information was referred to the Medical Officer on duty.

South East:
Miss Corrie to ask Dr McClelland.

West:
Dr Mitchell had incorporated in his "health notice" the question "Have you heard about AIDS? If you wish to know more you may ask the Medical Officer at the session in confidence or your General Practitioner or write to the Transfusion Director." The leaflets were available on request with the Medical Officer at sessions and Dr Mitchell wished to retain medical confidentiality. He had had one query, from Radio Clyde. He was reviewing the success of his approach.

N Ireland:
Dr McClelland had not yet received the leaflets but would make them available at donor sessions once he did.

Dr Wagstaff reported that there had been pressure from senior officials in England to give the leaflet to all donors attending. The Transfusion Directors had objected to this approach so a controlled trial was being run with some Centres handing the leaflet to every donor, others making them available at sessions and others sending them out with the call up letter.

Dr Cash agreed to ask the Director of the Blood Transfusion Service in Dublin how the leaflet produced there was being circulated and to send the Directors this information when received.

There was some discussion as to whether the SNBTA should have been given the opportunity to comment; it was concluded that it would be necessary only if a decision was taken to issue the leaflet to every donor.

The absence of reaction to the leaflet was welcomed but it was acknowledged that this might last only so long as there were no cases of AIDS.

Dr Urbaniak indicated that he intended to issue leaflets to STD clinics and it was agreed that this was an excellent approach which other Directors might wish to follow.

It was noted that DHSS wished a report in three months' time on the efficacy of the leaflet distribution and that SHHD were keeping the Minister briefed. They would like to know any difficulties which were being experienced and would wish to be informed if any research project (such as that mentioned at the previous meeting) was commenced.

It was noted that "illness notices" in Scottish Centres other than the West had not been amended. In England and Wales two questions had been added, namely - whether the donor had consulted his doctor recently, and whether he had experienced unexplained loss of weight. There was some discussion about how to handle prospective donations from self-declared homosexuals. It was emphasised that one could not guarantee to a self-declared monogamous homosexual that his donation would be used any more than one could guarantee this to any donor, and it was agreed that at the present time it was best not to take such donations in view of possible staff anxiety.

d) Central Management Services Report:

Blood: Record keeping and stock control (5)

Dr Cash reminded the meeting that the Scottish Directors had read the above report and considered whether it might be revised for use in Scotland. The SHHD officers had suggested that it was important first of all to ascertain what stock control was in force in Scotland and Dr Cash had undertaken to obtain the information. He had received three detailed responses so far and would report again once the other two had been received. It was acknowledged that a number of the recommendations in the report were already in force in Scotland or were about to be introduced.

Dr Wagstaff explained that in England and Wales the principal problems lay not in Transfusion Centres, but in hospital blood banks.

e) Purchase of Commercial Blood Products, Year to 31 March 1983 (8)

In relation to the problems experienced in obtaining information through Health Boards it had been agreed at the previous meeting that further enquiries should be made into the merits of instituting the purchase of all commercial blood products through the aegis of Regional Transfusion Centres. This had also been a recommendation in the Management Services Report quoted in 3d above. The following existing arrangements were reported:-

North:
no purchase of commercial products in recent years. Dr Whitrow would make a formal arrangement with the CAMO.

North East:
it was accepted practice (and a letter confirming this from the CAPO existed) that commercial blood products would be ordered through the Transfusion Centre except for FEIBA where there was no competing NHS product. The Directors felt that it was important to know how much FEIBA was being purchased and it was suggested that the equivalent NHS product was DEFIX.

East:
there was no formal arrangement with the CAMO but Dr Brookes would approach him.

South East:
Dr McClelland had confirmed that the Lothian Health Board had agreed to stand by an earlier decision that all commercial blood products should be purchased by the Transfusion Centre.

West:
it was not agreed policy in any of the Health Boards in the W of Scotland that the Transfusion Centre would purchase commercial blood products although Dr Mitchell would welcome the opportunity to do so. There was considerable discussion abouthow he might achieve this in a region as large as his where there were 40 haematologists and 4 cell separator units. He would welcome help from the SHHD and Dr Bell undertook informally to consult the Chief Pharmacist as to how the problem might be tackled. Dr Mitchell agreed to take no action until he had heard from Dr Bell. It was noted that the problem might in the end be resolved by the SHHD's views on the Central Management Services Report on record keeping and stock control of blood.

4. DEPARTMENT OF EMPLOYMENT SPECIAL INVESTIGATORS AND BTS

Dr Cash invited comments on correspondence which had been circulated concerning a telephone call and a subsequent visit by DOE Special Investigators to the Edinburgh Transfusion Centre in pursuit of information about the place of employment of a blood donor.

It was noted that the advice of the GMC was that confidential medical information should be divulged only in instances of serious crime.

5. ANTI-D TRIAL: WEST OF SCOTLAND

There had been circulated correspondence, including the draft protocol of a trial to be conducted in the Queen Mother's Hospital, Glasgow on antenatal anti-D prophylaxis which it was hoped would commence in November 1983 and for which Mr Watt had produced an extra quantity if vials of 250 i.u. doses.

Dr Mitchell reported that he had discovered that it would be impossible to obtain a significant number of cases from the Queen Mother's Hospital and that the Professor of Obstetrics there would find it difficult to persuade colleagues elsewhere to participate. It was agreed to take no further action until or unless Dr Mitchell was contacted by Professor Whitfield of the Queen Mother's Hospital.

Dr Urbaniak reported that the UK Joint Sub Committee on HDN (which he attended) would meet shortly and he would report to the Directors following this meeting.

There was discussion on who should issue to Rh(D) negative mothers the "green cards" which had been made available by the SHHD and it was concluded that the laboratory was the most appropriate place, particularly since a laboratory reference number was required on the card.

6. NEQAS: LOCAL ADVISER FOR SEROLOGICAL PROFICIENCY TESTING

Correspondence had been circulated concerning the agreed need for local advisers and the fact that the BTS felt that the adviser should in each case be the Transfusion Director or a Transfusion Centre consultant. The Scottish position was reported as follows:

North:
Position uncertain; Dr Whitrow would advise Dr Holburn of NEQAS that he had discussed the matter with his Transfusion Director colleagues who wished the local adviser from the North to be from the Transfusion Centre.

North East:
Dr Urbaniak was awaiting a reply from the NEQAS panel which was likely to be in the affirmative.

East:
The Transfusion Director.

South East:
The Deputy Director

West:
The Transfusion Director.

7. NBTS DIRECTORS MEETING 18 May 1983

Dr Mitchell spoke to his notes (which he had circulated) of the above meeting. There was discussion about the CBLA Research Committee and Dr Mitchell drew Dr Cash's attention to the fact that Dr Brian McClelland was a member of this research committee. Dr Cash confirmed that Dr McClelland had been invited on a personal basis. Dr Bell also served as an observer on the committee, representing SHHD. Dr Mitchell reminded his colleagues that the NBTS and Scottish Directors had both declined to support the concept of a Transfusion research committee and he was concerned by the attendance of a Scottish Director at the CBLA Committee. Dr Cash explained that he had been disappointed by the lack of support from the Scottish Directors for a Research Committee which he felt would fill the vacuum left by the former MRC Blood Transfusion research committee. He pointed out that the SNBTS Directors' view had not been unanimous and as an employing authority the CBLA had a right to establish such research commitees as it wished without formal reference to NBTS or SNBTS Directors.

8. WORKING PARTY ON SELECTION OF DONORS/NOTES FOR TRANSFUSION

A letter which Dr Brookes had written to Dr Cash on 23 August 1983 had been circulated. Dr Brookes explained that the Working Party, which had four members, had met only once and had taken most of its comments by correspondence The Chairman of the group (Dr Entwistle) appeared to be arranging a printing of the final version and seemed reluctant to let members of the Working Party see drafts. ~~It was noted that the~~ drafts should be referred to the bodies which had commissioned it, namely the NBTS and the SNBTS for consideration and perhaps also to DHSS Medicines Division since the "Red Book" on manufacturing blood products included a section on donor selection. It was agreed that Dr Brookes should approach Dr Entwistle again while Dr Cash would write to Dr Wagstaff on the matter.

A revised draft of "Notes for Transfusion" would be circulated to the Scottish Directors for final comment and Dr Brookes asked that her colleagues read this with attention since she was concerned that it contained some practices which would be considered ~~out of date~~ in Scotland and there might be, in consequence, a need for a Scottish version. It was agreed to continue the topic on the agenda of future Directors' meetings.

On the matter of collection in prisons and borstals it was noted that the Medicines Inspector had expressed concern at this practice. Owing to different circumstances in the Transfusion Regions the Directors had been unable to reach a consensus. The Chairman of the Working Party thought that the practice was diminishing in all regions in England and Wales. Dr Brookes felt strongly that donations should not be collected from prisoners because of the uncertainty about replies to questions concerning health.

It was reported that the practice had been raised at the Medicines Inspectors' Action Group who had referred it to the DHSS Administrative Division who confirmed that some Transfusion Centres in England still collected from prisons and borstals and that cessation of this practice would place them in difficulty. The NBTS Directors were due to discuss the matter and the DHSS would wish to consult the Home Office who had been anxious previously to encourage donation in prisons.

It was acknowledged that prisons and prisoners differed greatly from one place to another and some Directors felt that a blanket decision to cease visiting prisons would be a mistake. Dr Mitchell in particular felt that it would be unfortunate if such a recommendation was to be included in the "Red Book".

Dr Brookes undertook to circularise the English/Welsh Transfusion Directors and report back to the meeting.

9. BLOOD PACK FAULTS, W SCOTLAND BTS

Dr Mitchell described weaknesses which had been discovered in a significant number of packs in his region at the point where the donor line enters the pack and where a fracture could occur under lateral pressure. He had been very grateful to his colleagues who had supplied 1,350 packs, mostly of packed cells. He had operated an emergency service only to hospitals and had mounted special donor sessions. There had been one transfusion reaction.

10. DATE OF THE NEXT MEETING

Thursday 8 December 1983.