CONFIDENTIAL

MEETING OF THE SNBTS MEDICAL & SCIENTIFIC COMMITTEE
14 and 15 AUGUST 1991, SEMINAR ROOM, PROTEIN FRACTIONATION CENTRE, ELLEN'S GLEN ROAD, EDINBURGH

Present:
Professor J D Cash (Chairman)
Dr S J Urbaniak
Dr W Whitrow
Dr E Brookes
Dr D B L McClelland
Dr R Mitchell
Dr R J Perry
Dr C V Prowse
Dr R R C Stewart (Secretary)

In Attendance:
Dr A Robinson
Mrs S Shearer (Assistant Secretary)

1. **APOLOGIES**

An apology was received from Dr W McClelland.

2. **MINUTES OF THE PREVIOUS MEETING OF THE MEDICAL & SCIENTIFIC COMMITTEE HELD ON 15 and 16 MAY 1991**

2.1 **Comments**

Page 1: Dr Perry's name was omitted from those in attendance. Apologies are due to him.

Page 7: Item 3.4, para 3:
Insert 'SNBTS' before 'Transfusion Directors'.

Other than the above comments, the Minutes were accepted as a true record of the meeting.

3. **MISCELLANEOUS MATTERS ARISING FROM PREVIOUS MINUTES**

The Committee noted that matters arising from a Standing Item would be dealt with under that Standing Item.

Other matters arising would be dealt with under Miscellaneous Matters Arising.

3.1 **Bone Marrow Transplant - Unrelated Donor Panel**

Professor Cash thanked Dr Urbaniak for preparing an excellent report and invited him to speak to his paper. With regard to including Dr Crawford in Regional discussions, Professor Cash advised Dr Urbaniak that he was free to enlist the co-operation of whoever he wished.

ACTION

Dr Urbaniak spoke to his paper which contained a series of proposals.

Proposal 1: That the SNBTS accept the status quo regarding the Anthony Nolan Research Centre and work towards commonality between ANRC and the British Bone Marrow and Platelet Donor Panel, recognising that this may evolve to a joint UK panel.

(Dr Urbaniak stated that the ANRC is now operating acceptable standards having accepted all the fundamental points on donor selection developed by the UK BTS.

Professor Cash stated that the Department of Health and the Royal College of Pathologists are to develop guidelines on unrelated BMT, with particular reference to the ethical issues associated with the donor.)

This proposal was accepted.

Proposal 2: That no active steps are taken to recruit SNBTS marrow donors until approved documentation and procedures are in place.

This proposal was accepted.

Proposal 3: That all reasonable attempts are made to make the revised leaflets acceptable within the NBTS, to promote UK commonality and reduce printing costs.

This proposal was accepted.

Proposal 4: That the revised primary leaflet, after SNBTS/MSC approval, becomes mandatory throughout the SNBTS.

This proposal was accepted.

Proposal 5: That the updated secondary information for donors be mandatory within the SNBTS and, if required, distributed at cost to the NBTS Centres.
(It was noted that the secondary information for donors leaflet is to

be reviewed by Dr Gillon, who will submit it to Dr Urbaniak.)

This proposal was accepted.

Proposal 6: That BTS recruited bone marrow donors may see a Medical Officer for further explanation, if desired, but this is not mandatory provided the donor has received the secondary information leaflet.

(It was further noted that this leaflet is intended to give information to the donor without the donor seeing a Medical Officer. The leaflet says that the donor can see a Medical Officer if they wish.)

This proposal was accepted.

Proposal 7: That the recruitment and management of BTS bone marrow volunteers be organised through the respective RTC Donor Services Departments (not tissue-typing laboratories).

This proposal was accepted in principle.

Proposal 8: That SNBTS Centres type donors for HLA A and B only for initial bone marrow donor recruitment. Where possible lymphocytes should be cryopreserved for subsequent DR typing, either locally or at Bristol, by DNA/RFLP technology.

This proposal was accepted.

Proposal 9: That each SNBTS RTC use the standard BBMPDP disc format for reporting results direct to UKTS via floppy disc, with each RTC maintaining its own register of HLA-typed donors.

This proposal was accepted.

Proposal 10: That in due course consideration be given to incorporating the HLA panel/ register for each RTC within DOBBIN.

This proposal was accepted in principle, although Dr McClelland suggested that we need to get guidance from the IT unit on whether there should be a sub-file of DOBBIN on bone marrow donors only.

Professor Cash agreed to take this up with Mr Howe and Mr Moores and report back to the Committee. **JDC**

Proposal 11: All draft documentation and costings be completed by 6 November MSC meeting. A decision will be required at that time whether to start, or await consultation with BBMPDP.

(Dr Urbaniak confirmed that costings were still under discussion but that with HLA A and B typing only, a uniform cost of £8 + VAT per donor would suffice for the screening tests.)

This was accepted. However, Dr Urbaniak was requested to circulate leaflets etc to Members once they became available. SJU

Professor Cash once more thanked Dr Urbaniak for his excellent report.

3.2 **Procedure for Inspection of Private Hospital Blood Banks**

The Committee noted that the above document was formally issued by Professor Cash on 1 August 1991.

The Committee agreed that Professor Cash should raise the auditing of these procedures with the QA Group. **JDC**

Dr Mitchell expressed his concern that inspecting a private hospital blood bank may be seen as an accreditation and that the SNBTS would assume liability for performance of the blood bank.

Dr Perry suggested that the report of the inspection could include a disclaimer, stating the limitations of the inspection and that the inspection did not consider the competence of those employed in the blood bank. Members of the Committee expressed the opinion that this was the responsibility of the management of the blood bank.

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Professor Cash agreed to explore the liability position further and that such consultation would include the Central Legal Office. **JDC**

Professor Cash pointed out that the reason for the inspection was to ensure that blood products were being handled and stored appropriately so that, if recalled for NHS use, the RTC QA Manager would have confidence in the product.

3.3 **Adverse Event Reporting**

The Committee noted that the SOP was issued on 9 July 1991. Professor Cash stated that the QA Group would give consideration to expanding this to RTC products. **JDC**

3.4 **RTC Platelet Use**

In the light of comments from the SNBTS Board, it was felt that it would assist MSC Members if this topic was discussed against the background of an automation in blood processing. **This was accepted.**

3.4 (a) Semi-Automated Component Processing

WM/JS

It was agreed in principle that the Members endorse a policy on the introduction of semi-automated component processing.

It was noted that the NPBI and Baxter systems were now of comparable cost and that the decision on which to use was best left to individual Directors and their staff.

Dr Mitchell said that, in his opinion, there were many developments occurring in this area and he felt that his Region would require a fuller local evaluation before deciding to proceed with either system.

Dr Mitchell reported that he had requested that Dr Ala visit Law Hospital to talk on his experience with automated component processing and that other Members of the SNBTS would be welcome to attend. **RM**

3.4 (b) Platelet Production in the SNBTS: A Review of Current Trends and Future Developments

Dr Murphy joined the meeting at this point.

Dr Stewart spoke to his paper.

Dr Robinson expressed the opinion that there were insufficient data at present to say that apheresis platelets were the expensive option and advised the Committee that a formal costing was being undertaken in her Centre and the results could be made available to SNBTS colleagues if required. Professor Cash observed that all published reviews he had seen concluded that apheresis platelets were the more expensive option, if random platelets could be made available and all present welcomed Dr Robinson's proposal.

It was noted that there had been a 110% increase in use of random donor platelets between 1983 and 1991 but production had only gone up by 30%. It was further noted that approximately 30% of whole blood units processed to red cell concentrate were used to make platelets.

It was noted that the East RTC was making apheresis platelets as a standard product.

There are marked differences in the use of HLA-matched platelets between the Regions. Professor Cash asked Drs McClelland and Murphy whether the use of HLA-matched platelets will be subject to medical audit. This was confirmed.

While it was agreed that a lack of an increment in platelets after platelet infusion was of dubious value, Dr Murphy expressed concern that if audit showed that many patients were not getting an increment from random donor platelets, then demand for HLA-matched platelets may increase.

Dr Stewart's recommendations were:

(a) Platelet production and usage should be subject to annual review with a report on current trends presented to the MSC.

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(b) Routine platelet production should be primarily based on a random donor programme, with automated processing and using the buffy coat approach.

(c) Apheresis should be primarily reserved for situations where a single donor product is required.

These were accepted by the Committee. Each Centre should now plan to move forward on automated component processing at their own pace.

The difficulty for East RTC was noted and could be further discussed when the Leeds RTC costing data were available. Professor Cash suggested that the Laboratory Managers/PMLSO Group should convene to discuss the introduction of automated component prescribing and that Dr Murphy's input to this Group would be valuable. **JDC**

This was agreed.

Professor Cash agreed to take the Committee's support of automated component processing and buffy coat production method to the SNBTS Board. **JDC**

The Chairman thanked Drs Murphy and Stewart for preparing the paper.

Dr Murphy left the meeting at this point.

3.5 **HLA Reagents Supply**

Members noted that no further action was required as correspondence from Mrs Robina Balderson (UKTS) made it clear that UKTS would not consider abandoning supply of HLA reagents without full consultation with its customers.

3.6 **National Donor Deferral Register**

Members noted that Mrs Thornton had agreed to co-ordinate the development of this in consultation with Drs Galea, Gillon and others. A paper will be presented to the November MSC meeting. **MT**

3.7 **Tear Down Packs**

Members noted that Dr Perry had agreed to have his paper available for the November MSC meeting. **RJP**

3.8 **Any Other Business**

Members noted that Mr Bruce, Dr Follett, Mr Moores, Dr Prowse and Dr Stewart had been requested to produce an annual report for the MSC meeting on 6/7 November 1991. **MB/EF/ MM/CVP/ RS**

4. STANDING ITEMS

4.1 Standing Item : Blood Collection Programme

Matters Arising

Dr Galea joined the meeting at this point.

4.1.1 UK Standing Committee Red Book, Volume II

Members noted that Dr Galea and Mrs Thornton now served on Dr Wagstaff's Standing Committee on Donor Selection Criteria. They also noted the composition of the sub-committee on Blood Components, chaired by Professor Cash.

Dr Perry advised the Committee that a Plasma Fractions Review Committee had been set up.

4.1.2 AIDS Leaflet

Professor Cash advised the Committee that Dr Gunson was in some difficulty with the Commission on Racial Equality over the wording of the "Africa" section and that this was holding up further development of the leaflet. Therefore, there is no targeted date for issue of this leaflet.

4.1.3 Acceptance of Plasma for Fractionation and Donor Management

Professor Cash advised the Committee that Dr Gunson had informed him that he had seen a minute of a meeting which stated that BPL would accept plasma for fractionation which was anti-HCV positive by screening test but negative by confirmatory testing. Thus, plasma which is screen positive will be on hold, but will be released if confirmatory testing is negative. This will not be the case in Scotland.

Dr Perry agreed to raise this issue with NIBSC on behalf of the Committee. **RJP**

The Committee noted that Professor Cash had arranged a meeting to discuss use of the term "Medical Hold" and looked forward to receiving notification of the outcome from Professor Cash. **JDC**

New Items : Blood Colleection Programme

4.1.4 Donation Safety

The Committee noted that Mr McIntosh had requested that the MSC prepares a report for the Board on methods which may increase the safety of SNBTS products. These might include:

(a) Positive Donor Identification

(b) Donation Testing: Should ALT or Anti-HBc be added?

(c) Should first time donors' cellular products be discarded?

Members noted that Mr Moores had agreed to produce a paper for the November meeting of the MSC on the effect of first donation discard and/or outdating at 25 days on blood stocks during 1990/91, using data from DOBBIN. **MM**

4.1.5 (a) National Donor Health Check Guidelines

Dr Galea spoke to his paper "SNBTS Blood Donation Programme - Report for MSC Meeting August 1991".

(i) Donor Health Check List DHC1

Dr Galea confirmed that the comments of the May MSC meeting had been incorporated. It was noted that Dr Hopkins had alerted Dr Galea to the omission of contact with infectious disease.

It was agreed that Dr Galea will write to the Regions advising that they incorporate the following question in the Basic Minimum Standard Questions -"Have you been in contact

with an infectious disease, e.g. chicken pox, measles etc. within the past four weeks?" **GG**

This is an interim measure and this will be included in the DHC at the next revision.

(ii) Donor Consent Form

Dr Galea reported that it is planned to produce a standard national donor session record but this will take some time.

(iii) Basic Minimum Questions

MSC comments have been incorporated.

(iv) Health Information for Donors (DHI1)

MSC comments have been incorporated. It is now being issued in all new donor packs.

(v) Health Check for New Donors (DHC1(N)

It was noted that self completion forms for new donors and lapsed donors have been introduced in the South East.

(vi) Health Information for Blood Donors

It was noted that due to the delay with NBTS AIDS leaflet, orders for SNBTS leaflets can be placed immediately.

(vii) Thank you for Sharing your Health

This leaflet was noted.

(viii) National Medical Register

Dr Galea tabled the paper entitled National Risk Register (see Appendix I), which included categories of donors who may put themselves or the recipients at risk.

The Committee thanked Dr Galea for this.

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Dr McClelland agreed that donors who are a risk to themselves should be considered but the first priority must be to remove those who are a risk to the recipient and he would like to see this element expedited.

It was noted that permanently deferred donors could be removed at the RTC, i.e. it was not essential that this be done at the session.

It was agreed that the primary purpose of the National Medical Register was not to protect session staff but to protect recipients of SNBTS products.

It was agreed that the Register should be invoked at the RTC level initially and it could later be taken out to sessions.

Dr Galea sought the guidance of the Committee on the first priority.

It was agreed that this should be to exclude those proven to be a microbiological high risk or self-declared (proven or not) high risk.

(b) Audit in the Blood Collection Programme

Dr Galea confirmed he was liaising with Mrs Thornton with a view to determining the nature of an audit programme for the SNBTS Blood Collection Programme.

4.1.6 Blood Donations by W.O.S.C.O.P.S. Volunteers

Professor Cash proposed that WOSCOPS volunteers be deferred as blood donors.

This was agreed by the Committee. Professor Cash agreed to write to Dr Packard on this topic and copy it to Mr McIntosh. **JDC**

Professor Cash thanked Dr Galea for his contribution and Dr Galea left the meeting at this point.

4.2 **Standing Item : National Science Laboratory**

WM.

Nothing to report.

4.3 **Standing Item : Medical Audit**

New Items

4.3.1 The Minutes of the SNBTS Medical Audit Committee were noted. The Committee also were pleased to note that three projects had been funded by CRAG.

4.3.2 Medical Audit projects within the SNBTS

A list of the current SNBTS Medical Audit projects was discussed.

It was agreed that in future any proposals being submitted to CRAG shall be approved by the MSC beforehand.

4.3.3 CRAG : Working Group on Use of Blood and Blood Products

Professor Cash tabled a letter which Mr McIntosh had recently received from Dr Farquhar (Appendix II).

It was agreed that it would be valuable to have an SNBTS representative on the Working Group.

Professor Cash asked Dr McClelland to convey his congratulations to the Medical Audit Committee and requested that Dr McClelland ensure that copies of appropriate audit reports be made available to the Committee. **BMcC**

Dr Perry left the meeting at this point.

4.4 **Standing Item : Quality Assurance Programme**

Matters Arising

Mr Bruce joined the meeting at this point.

4.4.1 RTC QA Managers

The position regarding QA Managers in the North, East and North-East RTCs was noted by the Committee.

New Item

4.4.2 Update Report

(i) RTC Audit

The Committee noted that audit of the North and South East RTCs had been completed.

The audit of the West RTC was in preparation.

(ii) BS 5750/Noel Brown & Co Ltd

It was noted that a costed proposal will be presented to the SNBTS Board. Professor Cash asked Mr Bruce to ensure that Noel Brown & Co were clear that the SNBTS had not made a final commitment to go the full way to BS 5750. Mr Bruce said this was clear.

(iii) Sub-Groups

The work of the Sub-Groups was noted.

(iv) Proposals

Proposals, prepared by Mr Bruce and Mr Barr, were presented for the QA batch testing of HBsAg and Anti-HIV 1+2 tests. These were accepted by the Committee.

Professor Cash thanked Mr Bruce and Mr Barr for their efforts in this area.

4.5 **Standing Item : National Reagents Programme**

New Items

4.5.1 (a) Centralisation Process

Mr Bruce reported that the centralisation process was proceeding on course. National stocks of reagents were firm.

It was agreed that, once a clearer picture of demand was available, stocks would be quoted in weeks as well as in number of units. **MB**

(b) New Cell Lines

Mr Bruce reported that new A and B cell lines were currently growing well. These would be available for field trial in September/October. It was also planned to make a blend of these to produce anti A + B.

Mr Bruce reported that the master cell banks for IgM anti-D (CDM1) were now frozen. This would be for the production of a straight IgM reagent. The supernatant is currently under evaluation and it is noted that it detects a range of D antigens and misses only D6.

It is planned to field trial these in September/October.

A second IgM producing anti-D cell line (CDM2) produces an antibody which does not detect D5. It is planned to blend this with an IgG (ESD-1).

(c) Monoclonal Anti-D Reagents

Mr Bruce reported that such was the avidity of the monoclonal anti-D that a 'weak D' person who was previously classed as D negative would now be classed as D positive. Mr Bruce had performed a literature survey and could find no reports of reactions in patients who were weakly D positive who were treated with D positive blood products.

MY NB

Mr Bruce's only concern was that D6 is missed. However, he pointed out that many polyclonal anti-D preparations miss D6 also.

The Committee supported Mr Bruce's proposal that these reagents be accepted and that the recategorisation of weak D to D positive would be acceptable.

(d) SNBTS Complaint and Recall SOPs (Blood Grouping Reagents)

The Committee noted that the SOPs should be used for all local, national or commercially purchased reagents.

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It was noted that 'Complaints' had been chosen in preference to 'Product Defect' as it was felt it would give increased user feedback, e.g. problems with methodology sheets.

The Reagents Complaint and Recall SOPs were accepted by the Committee.

It was noted that the methodology sheets had been with the Users' Group and that their comments had been implemented, and it was agreed that it would be valuable for the RTCs to have further consultation with the local blood banks, where appropriate.

It was agreed in principle that items such as the methodology sheets should normally be brought to the MSC for approval, but in the present circumstance the methodology sheets could go to individual SNBTS Regional Transfusion Directors for comment.

The Chairman thanked Mr Bruce for his input. Dr McClelland suggested that a compendium of reagent and product inserts be produced. Professor Cash advised that this was under consideration.] *

4.6 **Standing Item : Microbiology Reference Unit/ RTC Donation Testing**

Matters Arising

Dr E Follett joined the meeting at this point.

4.6.1 (a) HCV Donation Testing

Members were asked to note that 1 September 1991 is the official start date for HCV antibody testing.

The Committee agreed that all products produced in RTCs and awaiting issue will have been HCV antibody tested by 5 September 1991.

The Committee also agreed that all RTC produced products residing in hospital blood banks will have been confirmed HCV antibody negative by 5 September 1991.

The Committee noted that plasma for fractionation which had been bled from donors before 1 September 1991 and not tested for HCV antibody would still be accepted by PFC after this date. However, plasma collected from donors and destined for PFC after 1 September 1991 must be HCV antibody negative.

Dr Stewart was requested to circulate the above section in advance of the Minutes. **RS**

(b) Confirmation Testing

Dr Follett tabled a protocol for HCV Confirmation Testing (Appendix III).

Dr Follett requested that he be given a single contact name for each RTC. The Regional Directors supplied this at the meeting.

Dr Follett explained the procedures of Confirmation Testing to the Members. It was noted that the Reference Laboratory will only do confirmation (RIBA 2) testing and will not re-test by ELISA.

Dr Follett stated that it is planned to have colour coded forms for HCV, HBV and HIV.

The Committee noted that Dr Follett and Dr Brian Dow had arranged a meeting for relevant RTC contacts on 27 August 1991.

Donor Counselling

The criteria for the initiation of donor counselling were discussed.

The following were agreed:

1. **Repeatedly ELISA reactive, RIBA 2 negative - kept on hold, not counselled.**

2. **Repeatedly ELISA reactive, RIBA 2 positive, PCR positive/negative - counselled.**

3. **Repeatedly ELISA reactive, RIBA 2 indeterminate, PCR negative - kept on hold, not counselled.**

4. **Repeatedly ELISA reactive, RIBA 2 indeterminate, PCR positive - counselled.**

Dr Urbaniak asked what should be said to an HCV positive donor who asks about his previous donations.

It was noted that it had been previously agreed there would be no look-back and this should be conveyed to the donor. It was noted that this matter might be reconsidered by the ACTTD. It was further agreed that the only person to be informed was the donor's GP.

The Chairman thanked Dr Follett for his valued contribution.

New Items

4.6.2 Yersinia Enterocolitica

It was noted that Dr Mitchell and Mr Barr have commenced a UK BTS survey.

It was agreed that once data were available, Dr Mitchell would circulate to colleagues. **RM**

4.6.3 Follow-up of Anti-HIV Positive Recipients of Blood (PHLS Study - Dr Janet Mortimer)

It was noted that this was a courtesy copy of a letter circulated to English, Welsh and Northern Ireland Regional Transfusion Directors which had been sent to Professor Cash.

4.6.4 West of Scotland Blood Transfusion Service - HCV 2nd Study

Dr Mitchell verbally reported the results of the study of the Abbott 2 versus the Ortho 2 kits. He reported that there was good concordance of detection with the results obtained with the first generation kits. He also reported that there were a couple of outliers with the Abbott kit which tested positive but could not be confirmed. Also there was one positive with the Abbott system which was not detected by the Ortho system.

However, as the full results are not yet in on the Ortho system, no firm conclusions could be made at present.

Dr Follett left the meeting at this point.

5. **MISCELLANEOUS NEW ITEMS**

5.1 **Health Equipment Information : Management of Medical Equipment and Devices**

The paper prepared by Professor Cash and the copy of HEI 98 were noted by the Committee.

Professor Cash proposed that the PMLSO/Laboratory Manager in each Centre be designated the Technical Servicing Manager, in terms of HEI 98, and that Chief or Senior Chief MLSOs should be Department Equipment Controller.

The Committee agreed this in principle and asked Dr Perry to arrange for members of his team to invite representatives of RTCs, Reagents Unit, NSL, and Microbiology Reference Unit to an open forum to discuss Management of Equipment. After this meeting it would be the responsibility of individual Regional Transfusion Directors to implement the recommendations in their Centre. RJP RTDs

RW

5.2 **Hepatitis B Immunoglobulin Leaflet**

Members noted the requirement of the MCA that dosage be quoted in iu, not in ml.

The Committee accepted Dr Crawford's comments on the paediatric dose and approved the revised leaflet with the paediatric dose changed to 500 iu. Dr Stewart agreed to convey this to Dr Cuthbertson. RS

Dr Perry pointed out that a 'Pregnancy Warning' would need to be included. **This was agreed.**

Dr Perry suggested that, to increase the life span of leaflets, the wording of the section 'Safety - Side Effects - Warnings' of all immunoglobulin leaflets should read:

> "Each plasma donation used to manufacture this product is carefully screened for the presence of agents capable of transmitting infectious disease in accordance with the requirements of the National Control Authority."

PLY

Dr Perry's proposal was accepted.

5.3 **Anti-Cytomegalovirus Immunoglobulin Leaflet**

Dr Stewart reported that the leaflet had been circulated and comments incorporated. He also stated that Dr Yap recently had requested that the last sentence of Prophylaxis of Infection be changed to read:

"Bone marrow allograft recipients who are CMV positive and whose donor marrow is CMV negative may be at risk of infection, and prophylaxis may be considered."

This was approved by the Committee.

5.4 **Supply of Human Sera for NEQAS Purposes**

The Committee noted that English and Welsh RTCs are now charging for sera for NEQAS purposes while SNBTS do not.

Professor Cash proposed that the MSC recommends to the SNBTS Board that whenever the SNBTS supplies reagent material in an area which operates a cross-charging arrangement, the SNBTS should comply and charge for this supply.

The Committee supported Professor Cash's proposal and requested that he take it to the Board. **JDC**

5.5 **Therapeutic MCAb : Anti-D : Ethics of Clinical Use**

Professor Cash reviewed the background to this topic and invited Dr Urbaniak to speak to his paper.

Dr Urbaniak introduced his paper saying the major concerns were safety and efficacy. He said in his opinion the safety issue could be overcome as it had been with other therapeutic monoclonal antibodies. He said efficacy demonstration would be more difficult as this would require the trialing of a new product against one which has a proven efficacy and safety record. He reported that Dr Fraser in Bristol was doing a study in which monoclonal anti-D was given intramuscularly at the same time as labelled D positive red cells were given to D negative volunteers. Dr Urbaniak reported that the data for this study should be available in December 1991.

Dr Urbaniak's paper contained a series of proposals. These were as follows:

Proposal 1

Concerns about safety of monoclonal anti-D can be satisfactorily addressed and are not an impediment to implementation by clinical trials.

Agreed.

Proposal 2

That the PFC monoclonal production unit maintain a holding position meantime but no new developments are initiated, as agreed by the SNBTS Board.

Agreed.

Proposal 3 (Proposal 2 in paper)

That the SNBTS continue to produce monoclonal anti-D cell lines to generate a portfolio of IgG1 and IgG3 cell lines which are optimally active by current *in vitro* methods. A minimum of 3 of each should suffice.

Agreed.

Proposal 4 (Proposal 3 in paper)

That an expert group be set up to oversee and co-ordinate the above, maximising the use of current expertise and facilities.

Agreed

Proposal 5 (Proposal 4 in paper)

That the SNBTS continue to plan to take selected monoclonal anti-Ds through the initial stages of red cell clearance experiments and assess efficacy compared with competitors. Further steps to *in vivo* protection studies would depend on success at this stage.

Professor Cash pointed out that the SNBTS Board has decided that the SNBTS will not make therapeutic grade monoclonal antibodies.

Proposal 6 (Proposal 5 in paper)

That the SNBTS explore the possibility of developing synthetic D antigen, with a view to replacing human RBC as the immunogen for polyclonal anti-D production.

Agreed in principle.

Professor Cash suggested that the formation of an expert group be taken up by PDG. Dr McClelland suggested that a relevant medical input, other than Dr Urbaniak, may be helpful to the group. **This was agreed.** Professor Cash is to come back to the Committee with proposals. **JDC**

Dr McClelland expressed the view that marketing of a monoclonal anti-D may raise the issue of the ethics of boosting donors to get a polyclonal product. Plasma-derived anti-D may be viewed as old fashioned.

It was agreed that Drs Urbaniak and McClelland bring back to the Committee proposals on looking back at boosted anti-D donors to determine the safety. **SJU/ BMcC**

Professor Cash thanked Dr Urbaniak for his expert and comprehensive review of the topic.

5.6 **SNBTS Bone Bank Guidelines**

Dr Galea's letter was discussed. Dr Urbaniak pointed out that the Department of Health had requested the British Orthopaedic Association to set up guidelines. The Department will issue these as official guidelines. Dr Urbaniak agreed to speak to the Chairman of the group preparing the guidelines prior to their completion. **SJU**

Professor Cash suggested that Dr Galea discuss the position with Mrs Thornton and Dr Susan Lumley and bring back SNBTS A-Z guidelines for bone banking to the MSC. Meanwhile Dr Urbaniak could liaise with the British Orthopaedic Association. **GG**

This was agreed.

Professor Cash will discuss with Dr Galea. **JDC**

5.7 **Donation Archive Samples**

Members of the Committee were asked to note that space was available at Excel for samples from the West and North RTCs only. Other RTCs would need to make local arrangements. **RTDs**

Meanwhile Professor Cash will discuss further with Dr McIntyre and request that they review the requirement to keep all samples indefinitely. **JDC**

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5.8 **Transportation of Blood Donations from Donor Sessions to RTCs**

The draft recommendations of the Blood Transportation Working Party of the Head Laboratory Scientists Committee of England and Wales were noted.

It was agreed that this and associated issues be examined by a group, chaired by Dr Perry, which should include Drs Murphy and Prowse.

It was noted that there were essentially three questions:

(i) What is the most appropriate temperature for transportation and holding of whole blood?

(ii) What is the most appropriate temperature for separating components?

(iii) What is the most appropriate time for holding at this temperature?

Dr Perry agreed to present a progress report to the next meeting of the MSC. **RJP**

5.9 **Research Audit**

Professor Cash's paper was noted.

It was agreed that Drs Urbaniak, Mitchell, Perry, McClelland and Prowse should meet with Professor Cash (arranged for 31 October 1991) to discuss methods of audit and take proposals back to the MSC.

Dr McClelland suggested that each Director ask his scientists for proposals that they would wish their Director to take up at the meeting on 31 October 1991.

Professor Cash pointed out that it was an audit of projects, not of scientists.

5.10 **Vial Size of IVIgG**

The Committee noted the plan to introduce a 5g vial of IVIgG in addition to the current 3g vial.

5.11 **National Advisory Committee for Scientific Services**

It is proposed to form a Working Group to consider 'Specifications for Essential Laboratory Services and Facilities' chaired by Dr Robert Cumming of Stobhill Hospital.

It was agreed that Professor Cash should write to Dr A McIntyre requesting that the SNBTS be represented on this Working Group. **JDC**

5.12 **Proposed Mechanism for Blood Movements between SNBTS and NBTS**

It was agreed that North-East, East, South-East and West RTCs will advise SNBTS HQ of RCC available for 'transfer' (not export) daily on their blood stocks return.

Dr Whitrow will review the minimum stock of the North RTC, and anything in excess of these can be considered available for transfer if required. **WW**

Dr Stewart agreed to reissue a modified schedule. **RS**

6. **DATE OF FUTURE MEETINGS**

3/4 March 1992
13/14 May 1992
12/13 August 1992
4/5 November 1992

7. **DATE OF NEXT MEETING**

6/7 November 1991

8. **ANY OTHER BUSINESS**

Dr McClelland's letter on Resuscitation Response Times was tabled (Appendix IV).

Dr McClelland asked the Committee to note that the 5 minute timing was arbitrarily chosen and suggested that the guidelines should be left open without a specified call-out time. He suggested wording like "Doctors should be available to supply medical cover at the discretion of the Regional Transfusion Director".

It was agreed that there was no difficulty with sessions in RTCs but that sessions outside the Centre should have sessional medical officer cover.

Professor Cash agreed to rewrite and issue the guidelines. **JDC**

Professor Cash thanked the Members for their valued input over two long and very productive days.