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CONFIDENTIAL

MEETING OF THE SNBTS MEDICAL AND SCIENTIFIC COMMITTEE 9 AND 10 MARCH 1993, CONFERENCE ROOM, SNBTS HEADQUARTERS, ELLEN'S GLEN ROAD, EDINBURGH

Copy for circulation to Policy Group.

Present:	Professor J D Cash (Chair)
	Dr W Whitrow
	Dr G Galea
	Dr S J Urbaniak
	Dr C V Prowse
	Dr E Brookes
	Dr D B L McClelland
	Dr R Mitchell
	Dr R J Perry (10 March Only)
	Dr W M McClelland (9 March Only)
	Dr R R C Stewart (Secretary)
In attendance:	Dr D Lee (9 March only)
	Dr A Keel (afternoon of 10 March only)
	Ms V Miller (Assistant Secretary)

Title for file

Meeting commenced at 10.45 am on 9 March and 10.45 am on 10 March 1993.

ACTION

1.0 APOLOGIES

Dr Perry submitted his apologies for being unable to attend on 9 March. Mr Bruce also submitted his apologies. Professor Cash welcomed Dr Galea as a new member of the group.

2.1 MINUTES OF THE SPECIAL MEETING OF MEDICAL & SCIENTIFIC COMMITTEE ON PES WHICH WAS HELD ON 15 AND 16 SEPTEMBER 1992

2.1.1 The comments submitted by Dr Prowse were accepted.

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2.2. MINUTES OF PREVIOUS MEETING OF THE MEDICAL AND SCIENTIFIC COMMITTEE HELD ON 10 AND 11 NOVEMBER 1993.

2.2.1 The amendment proposed by the Chairman was accepted.

2.2.2 Comments:

The comments submitted by Dr Prowse were accepted.

3.0 MISCELLANEOUS MATTERS ARISING.

3.1 SNBTS HLA Tissue Typing Working Group.

i) *An SNBTS Tissue Typing Strategy for the next 10 years.*

Dr Yap spoke to his paper. He reviewed some potentially conflicting issues, and presented a series of proposals:

In a 5 year time span:

(a) Concentrating SNBTS Tissue Typing resources on Glasgow, Edinburgh, and possibly Aberdeen. The position of Dundee and Inverness laboratories will need to be clarified with the Purchasers.

(b) Concentrate Class I and II typing in only one or two centres by a DNA/PCR method.

(c) Link in these developments with centralisation of other laboratory aspects of the SNBTS.

(d) Show that these developments are cost effective.

(e) Show that the proposals are acceptable to the local purchaser ie. most clinical services will become purchaser driven.

What was AH getting at?

The Committee welcomed Dr Yap's proposals but in the light of comments made by Dr Keel that discussions would take place to maintain a measure of co-ordination of transplantation throughout the SHS, members agreed it would be premature to consider rationalisation of the SNBTS tissue typing programme.

ii) *The need and possible strategies for the MHC Class II testing of BMT donors*

Dr Yap talked to his paper which outlined considerations for routine Class II testing of BMT donors. His recommendation to the SNBTS for a cost effective approach was that the 'store and save' for class II PCR alternative be adopted for 1994/95. Dr Yap proposed that leukocyte aliquots from all SNBTS donors from the panel could be routinely stores at -20°C in 1993/94 for the UK BBMDP, assuming that the costs for a -20°C freezer and racking can be identified in the approaching financial year.

The Committee accepted Dr Yap's proposals that all Centres introduce, as soon as possible a policy of storing leucocytes such that Class II PCR studies could be done at a later date. RTDs

(iii) *Liaison with NBTS*

Professor Cash agreed to attempt to determine whether the NBA will take an interest in this area and would write to Dr Gunson, once the NBA was appropriately established. JDC

3.2 TISSUE BANKS - SNBTS FUTURE DEVELOPMENTS

i) *The Tissue Banking Group*

a) Minutes of the meeting on 1 December 1992 were noted. Dr Urbaniak informed members that all objectives set out over the past year have been met.

b) Dr Urbaniak briefed members on the update report from the SNBTS Tissue Banking Group meeting on 22 February 1992, prepared by Dr Lumley, and previously circulated to Members.

ii) *Cornea Transplants*

SJU

Professor Cash presented figures provided by UKTSSA and requested by MSC, giving information on Scottish sourced corneas: place of use, and Scottish Cornea Transplants: source of tissue. Dr Urbaniak pointed out that the figures did not include transplants using locally donated corneas. He agreed to find out the total number of corneas used for transplants.

3.3 NATIONAL KLEIHAUER QA EXERCISE

Dr Urbaniak informed members that the first SHS Kleihauer QA Exercise had taken place during the week beginning 22 February. Results had been received from all five RTCs and fifteen participating hospital laboratories. His initial observations show an interesting scatter of results. A full report will be available in due course. SJU

Professor Cash thanked Dr Urbaniak for his update.

3.4 QUARANTINED CLINICAL FFP, CYROPRECIPITATE AND VIP: UPDATE

a) Accredited FFP

Members noted Dr Mitchell's paper on the West RTC approach to quarantined FFP.

It was agreed that this matter be shelved at the present time.

b) VIP

Dr Prowse briefed members on the current position:

i) Octapharma has been refused a CTX. A meeting between Octapharma and the MCA was being arranged.

ii) CRTS Lille is in the process of applying for a CTX. Once details have been obtained, a meeting will be held with MCA.

iii) Dr Prowse was continuing discussions with Springe with a view to obtaining an agreement for use of the methylene blue process. Mr Ian Hardie had been invited to assist.

Dr Prowse advised members that the most attractive site for producing VIP appears to be PFC, where good transport arrangements are already available.

3.5 OPERATING/RELEASE PROCEDURES FOR NATIONAL FROZEN CELL BANK

The documents entitled 'Procedure for the ordering and issue of frozen/recovered red cells for transfusion' and 'Procedure for ordering and issue of accredited red cells for rhesus immunisation' have been withdrawn, Dr Peterkin will prepare new documents for the next meeting. MP

3.6 FUNCTION AND MEMBERSHIP OF THE MSC

Dr Galea led the discussion on 'Some views on the MSC with proposals for change'. Dr Galea informed members of the views relayed to him by consultants and scientists located in the 5 regions. The main concerns expressed were:

i) *Communication problems*

Many consultants felt they were not appropriately briefed on the medical and scientific affairs of the SNBTS. only full members will see this

ii) *Membership of MSC*

It was agreed that further consideration should be given to enlarging membership of the Committee. Consultant with National service responsibilities. ALL

iii) *Development of Expert Groups*

The members noted that this was currently taking place and this would give consultants better access to the MSC and better involvement in SNBTS affairs.

Members noted that the function and membership of the MSC should be further discussed in the future, and that it should be taken up with the SNBTS Consultants Group. JDC

4. STANDING ITEMS

4.1 BLOOD COLLECTION PROGRAMME

Mr Moores joined the meeting at this point.

4.1.1 Regional Minimum Stock Levels

Mr Moores spoke to his paper. He informed the members of the calculated minimum stock levels required to maintain supply to match regional, national and 'the world' demand (see below).

Members agreed that a decision on re-examination of the first time donor policy in the light of the data of blood stocks should be deferred until Dr Stewart had produced estimates of the number of first time donors with HIV or Hepatitis C in the 'window' period. RS

The minimum stock level for each blood group for each centre calculated by Mr Moores is appended (Appendix 1).

It was noted that the stock figures proposed by Mr Moores would be of assistance in future discussions of red cell concentrate movements.

4.1.2 Progress update

Dr Galea updated members on the Blood Collection Programme. The Donor Consultants Group met on 19 February 1993.

i) *Management of Professional Staffing at SNBTS Donor Sessions*

GRO-C

LC

MSC members noted that the Donor Consultants' Group hopes to conduct a pilot study in the West of Scotland of Donor Sessions run solely by nurses. Dr Galea agreed to report back to the MSC on behalf of the Donor Consultants' Group. Dr McClelland informed members of discussions on extending the pilot study to the South East, but that this SEBTS development would be an integral part of the SNBTS Donor Consultants co-ordinated investigation. GG

ii) *Phlebotomists at Sessions*

Dr Galea proposed that due to other developments taking place it was premature to discuss this at present. **The Committee agreed with this proposal.**

iii) *National Medical Register*

GRO-C: JG

The Donor Consultants Group proposed that with the change in the HIV criteria whereby donors in certain high risk categories are subjected to a 2 year exclusion, such temporarily deferred donors should not be entered on the NMR. Professor Cash asked members to support this proposal. This was agreed.

iv) *SNBTS Policy of Wearing Gloves at Sessions*

Professor Cash asked for members to approve that the SNBTS policy on minimum standards should be in line with the NBTS Transfusion Directors' policy. The policy is that any staff member who has cuts or abrasions on their hands must wear gloves. Gloves may be worn by other members of staff at their discretion. **The members agreed to this policy.**

v) *Update of SNBTS Medical Selection Guidelines and Associated Literature.*

It was noted that this is still under discussion by the Donor Consultants' Group and once agreed by them will be brought to the MSC. GG

vi) *Donor Selection Procedures: Intensive Interviewing*

The members noted that data from the USA suggest that face to face interviews with donors significantly enhances high risk donor exclusion. The benefits of computer interviewing were mentioned and it was agreed that careful consideration of cost would be required. Dr Galea reported that a meeting of the Donor Consultants with representatives of the Microbiology Reference Unit is to be held in summer 1993 to assess the results of the evaluation exercise which had been underway in SEBTS. Dr Galea will report back to MSC thereafter. GG

GRO-C: JG Plans for research study? Seek SNBTS funding for project?

vii) *SNBTS Donor Selection Symposium Evaluation*

Professor Cash was asked to congratulate the organisers of this symposium held in the Royal College of Physicians (Edinburgh) in November 1992. It was also noted that a second Symposium on donor selection is planned for Spring 1994. JDC

4.1.3 Annual Report of the Blood Collection Programme

This was approved by the Committee.

4.1.4 Staffing of SNBTS Donor Sessions

This was covered under 4.1.2 (i) and (ii).

Mr Moores left the meeting at this point.

4.2 NATIONAL SCIENCE LABORATORY/PRODUCT DEVELOPMENT GROUP

4.2.1 Guidance on Record Keeping and Supervision of Research and the SNBTS with Comments Addressing Fraud

The issue of these guidelines was noted. This item is now off the Agenda.

4.2.2. Options for the Provision by the SNBTS of Virally Inactivated Plasma (VIP)

This is covered under item 3.4.

4.2.3 Gene Therapy - Potential for the SNBTS

Dr Prowse confirmed that a meeting of interested parties had taken place in Edinburgh in January 1993. There appeared to be the development of an opportunity for interested parties in the Edinburgh area to come together to form a gene therapy programme. Dr Prowse will be involved in this exercise and will keep colleagues briefed. It was noted that this was in line with the previous decisions of the MSC to proceed with gene therapy in a single centre in the Edinburgh area. CVP

Professor Cash informed members that the Government Advisory Committee on Science and Technology report has been published. The report has a section on Gene Therapy and it is the view of the Committee that the BTS will have a role in Gene Therapy.

4.2.4 Optional Appraisal for Fibrinogen for Infusion

Dr Prowse spoke to his paper. His proposals were:

(i) Submit CTX for FFI prepared from outdated plasma with view to initiating clinical trials, in May/June 1993.

(ii) Supply FFI from plasma sources currently available. With current estimated demand this would allow demand to be met until July 1994. Adoption of a half size for fibrin sealant could extend this further.

(iii) Confirm ability to prepare stable FFI to specification, from side fractions of the HP-VIII process. This will require a second CTX and trial and will need to be in place by December 1993 to ensure continued supply of FFI, and fibrin sealant, against projected demands. An interim report covering these matters to be prepared by August 1993. CVP

These proposals received the support of the MSC and it was agreed that they should be recommended to the Board. Members noted that the Board may wish to reduce the priority of this project for financial reasons.

4.2.5 Monoclonal Anti-D Rhesus Co-ordinating Group

Members were asked to note the strict confidentially of this item. Drs Urbaniak and Prowse reviewed progress to date. They presented the following proposals:

(i) That SNBTS, in Aberdeen , undertake a planned *in vivo* assessment in human male volunteers, of selected candidate therapeutic monoclonal antibodies. If possible this should be undertaken in collaboration with Lille CRTS (under cover of appropriate agreements) and with EEC grant funding.

(ii) That the PFC undertake to provide at least two antibodies, selected from the panel already subjected to *in vitro* assessment, of clinical grade.

(iii) That EEC funding for co-ordination of studies, given agreement from Lille CRTS and PFC, be pursued.

(iv) That *in vitro* assessment of further (IgG) monoclonal anti-rhesus D antibodies generated in the Glasgow and West of Scotland BTS be pursued to provide further candidate therapeutic antibodies.

HOW MUCH PLAN??

The proposals received the support of the Committee subject to the availability of appropriate funding. **It was agreed that it was appropriate at this stage to plan to take the project through to phase 1 (volunteer) studies.** SJU/CVP

4.2.6 Annual Report of the National Science Laboratory

The Annual Report was noted and approved by the Committee. **It was agreed that it be passed on to the Board.** RS

4.2.7 Annual Report of the Product Development Group

The Annual Report was noted and approved by the Committee. **It was agreed that it be passed on to the Board. The proposals detailed in the appendix to change the list of product development priorities were agreed by the members.** RS

4.2.8 Report of Audit of SNBTS R&D Activities

Members noted that this report has been deferred.

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4.2.9 Factor VIII Concentrate and HAV Transmission

Dr Prowse briefed colleagues and made the following points:

i) a solvent detergent treated, ion exchange purified factor VIII concentrate manufactured by Octapharma had been implicated in the transmission of HAV

ii) there are no reports of transmission of HAV with PFC or CRTS Lille high potency factor VIII

iii) batches of PFC high potency factor VIII are PCR negative for HAV

iv) a meeting is being arranged through EPFA of manufacturers who use solvent detergent and ion exchange to determine whether there is a problem.

4.2.10 Recombinant Human Monoclonal Anti-Endotoxin and Sepsis Intervention Group

Members noted the update report prepared by Dr Prowse. It was noted that the British Biotechnology Group have decided not to take up this project. Dr Prowse advised that he intended to liaise with Mr Ian Hardie with the intention of finding a collaborator for the next step of trials in volunteers. **This was supported.** CVP

4.3 MEDICAL AUDIT COMMITTEE

4.3.1 Annual Report of the Medical Audit Committee

The Medical Audit Committee has continued to monitor the progress of 4 CRAG funded projects. The audits are all on schedule and are expected to be submitted on time. Dr McClelland agreed to send Professor Cash a copy of the final report. The members approved the Annual Report. Professor Cash agreed to forward the Annual Report to Mr McIntosh for onward transmission to CRAG. JDC

Copied to Dr Ghosh by GRO-C 1/5/93

4.3.2 Medical Audit of Anti-D Programme

Members noted the proposals prepared by Dr Ghosh and that they had been approved by the MAC, and recorded their support. JDC

GRO-C: Study planning now complete. Tentative launch Asc.

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4.3.3 Proposal for Audit of Medical Input to SNBTS

It was noted that both the MAC and MSC supported the proposed audit of RTC clinical services. **It was agreed that this should be discussed by the SNBTS Medical Consultants' Group.** DBLMcC

4.3.4 Rhesus (D) Negative Platelets: Availability

To MAC Agenda - see Galea letter

The MSC supported the MAC's view that this was an important matter to audit and invited Dr McClelland, as chairman of the MAC, to make this part of the national Medical Audit Programme. DBLMcC

4.4 QUALITY ASSURANCE PROGRAMME

4.4.1 RTC Quality Programme - Update

Members noted there remained significant outstanding problems relating to accommodation in the North and West RTCs.

4.4.2 SNBTS QA Group Audit Programme

The current SNBTS QA Group Audit Programme, directed primarily towards the quality of plasma destined for PFC, has been successful and is presently coming to a close. Members noted that it is hoped that an audit of the donor programme will begin in 1993.

4.4.3 Incident/Event Reporting Systems within the SNBTS

Members noted that Dr Stewart is preparing an overview of reporting systems within the SNBTS, and will present this to a future meeting of the MSC after it has been considered by the SNBTS QA Group. RS

4.4.4 Annual Report of the SNBTS QA Group

Members noted that the annual report of the QA Group has been deferred to the next meeting, due to the desire of this group to include local RTC quality activities. MB

4.5 NATIONAL REAGENTS PROGRAMME

4.5.1 National Reagents Programme - Update

It was agreed that continued development of this programme was heavily dependent on the availability of funding. This may require discussion by Management Board. JDC

4.5.2 Costing Study

Members warmly welcomed the news that the costing study is underway, and looked forward to being briefed in due course. MB

4.6 MICROBIOLOGY/DONATION TESTING

Dr Follett joined the meeting.

4.6.1 National Donation Testing Programme: Update Hit Rate Summary

Dr Follett's report was noted. Members looked forward to receiving more detailed information, including trends, in the annual report. EF

4.6.2 Anti-HCV Test Kit Evaluation (Murex/Ortho)

Murex

i) Members concluded that there had been some misunderstanding within Murex of the requirements of the SNBTS. These had been cleared up. Dr McClelland agreed to send a copy of the Edinburgh Anti-HCV Test Kit Evaluation report to Dr Mitchell. DBLMc

Ortho

ii) The members noted that a final report on the evaluation of Ortho HCV 3.0 ELISA is imminent. RM

4.6.3 Abbot Prism Study

The study is planned to commence in Spring 1993 and Dr Mitchell had nothing further to add at this time. RM

4.6.4 HIV 'Window' Phenomenon

This study had now been completed. Dr Mitchell reported that there is no evidence of HIV window phenomena occurring in Scotland other than the one already reported in the West of Scotland in 1986.

4.6.5 PCR Testing Rhesus D Positive Donations for Boosting

GRO-C: JG

The Committee concluded that provision should be made for prospective PCR testing for the presence of HBV, HIV and HCV of Rhesus D positive donations used for boosting as soon as was possible. It was noted that Dr Urbaniak was reviewing the SNBTS position in the light of the new edition of the Red Book and would incorporate this policy decision by MSC into his recommendation. SJU

4.6.6 B19 Parvovirus: PCR Plasma Pool Testing

Members noted that the study is on schedule to take place in spring 1993. Dr Yap would report in due course. PLY

4.6.7 Reinstatement of Previously HCV Screen Positive Donors to the Panel

GRO-C: JG

Members welcomed developments in this area (see 4.6.12) which will do much to relieve concerns over the donors who were HCV screen positive with previous test kits.

4.6.8 Annual Report for the Microbiological Reference Unit

Members noted that the annual report of the MRU has been deferred to the next meeting. EF

4.6.9 Proposals for and SNBTS Accreditation Procedure for Microbiology Donation Testing Kits

GRO-C: JG

The modified proposals contained in the paper presented at the meeting (see Appendix II) for an SNBTS accreditation procedure of donation screening kits were approved by the members.

4.6.10 Anti-HBc Donation Testing

Dr Mitchell, Dr Follett and Professor Cash briefed colleagues on developments in this area. Members noted the enclosed letter and algorithms prepared by Dr Mitchell.

Professor Cash informed the members that the start date for routine anti-core donation testing is likely to be some time in autumn 1993. It was noted that the SNBTS was making a substantial contribution (SEBTS, WBTS and MRU) to the UK BTS Advisory Committee's deliberations which will lead to ministerial advice of the programme.

Professor Cash agreed to put together a group consisting of Mr Barr, Dr Follett, Mr Bruce and representatives of the IT unit to consider the impact of introduction of anti-HBc testing on current procedures including DOBBIN. JDC

4.6.11 Behring Anti-HIV Test Kits Evaluation

Behring have requested that their Anti-HIV kit be evaluated by the SNBTS. At present none of the members expressed an interest in introducing the test in their Region. **Professor Cash agreed to inform Behring of this decision.** JDC

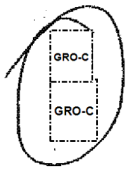
4.6.12 Draft Proposals for a Generic Protocol for Re-Admission of Blood Donors to the Active Panel

Members welcomed this development, but noted that its implications may be complex and proposed that it should be considered in the first instance by the group defined in 4.6.10.

Dr Follett left the meeting at this point.

4.7 PROTEIN FRACTIONATION CENTRE

4.7.1 Acceptance of Plasma Fractionation: HCV Anti-body Testing



Dr Perry informed the Committee that Dr Metters (DoH) is in the process of consulting with Ministers on the use of screen positive confirmatory test negative plasma for fractionation. It is thought likely that the decision will be that such plasma should not be used. Dr Perry will update colleagues as required. RJP

4.7.2 Ante-Partum Prophylactic use of Anti-D IgG

i) *Update on CPMP Recommendations on Dose*

Dr Perry agreed to write to the MCA and finalise the legal status of the core summary of Product Characteristics in the UK. At present there are no plans to make a 1250 IU dose. RJP

ii) *Meeting with Scottish Obstetricians*

The Scottish obstetricians met in Edinburgh on 12 February 1993. Drs Urbaniak and Stewart advised the Committee that there was no immediate demand for routine ante-natal prophylaxis from the obstetricians. They had agreed to consult widely within their group and would advise the SNBTS of the result of this consultation when they meet again in 2-3 months. Drs Urbaniak and Stewart agreed to maintain contact with the group. RS/SJU

Members supported Dr Urbaniak's proposal that the collection target for 1993-4 should remain at 122 million IU and Dr Stewart was asked to convey this to the Board.

iii) *Ante-Partum, Anti-D: Cost Benefit Analysis*

Dr Urbaniak will present a report in due course. SJU

iv) *BBTS HND Special Interest Group*

The letter from Professor Cash to Dr Contreras was noted.

v) Members were informed that Obstetricians in the Borders plan to perform a study to audit the effectiveness of the delivery of ante-natal anti-D and to establish some efficacy data over a year of ante-natal use to compare with historical data. Dr McClelland had met with obstetricians involved and had been asked to supply anti-D for the study. The members agreed that the study should be supported. Professor Cash requested Dr McClelland to ask the Obstetricians in the Borders to maintain close liaison with the Scottish Obstetricians' Group. DBLMc

4.7.3 Hepatitis A Antibody in Normal Pools

Dr Gillon spoke to his paper. It was noted that the reduction in HAV antibody level in PFC's normal IgG is accelerating. Dr Gillon advised members that, based upon discussions with Dr Cuthbertson, 300 litres of HAV plasma will be required to address this problem. He reviewed the options for procurement of this plasma, and recommended that selected whole blood donors be screened.

The Committee supported this recommendation.

It was noted that the requirement for augmentation of the pool was not a matter of urgency and Dr Perry estimated that it would be acceptable if delivered in 9-12 months. **Dr Gillon agreed to set up a group to consider the implementation of his proposals. Professor Cash agreed to enquire about the financing of HAV plasma collection when Dr Gillon had submitted a final proposal.** Professor Cash thanked Dr Gillon on behalf of the members. JG/JDC

4.7.4 Plasma Products Made from Material not Screened for anti-HCV

Dr Perry agreed to report back on the response from the MCA to an application which had now been lodged by PFC, for continued issue of anti-D IgG made from non-HCV screened plasma. RJP

4.7.5 Heat Treatment of HPVIII

Members noted that Scottish Haemophilia Directors have expressed the preference for Factor VIII concentrate which has been terminally heat treated. A review by the Product Development Group is planned in April/May and MSC would be kept briefed. RJP/CVP

4.7.6 High Purity Factor IX Concentrate

Dr Perry updated colleagues. Two batches of Factor IX concentrate have been made and another batch is due later in the month. A clinical trial is planned in the autumn which is presently on schedule.

4.7.7 Update on Phase III/IV

Dr Perry updated members on progress. At present the project is one month behind schedule.

4.8 INFORMATION TECHNOLOGY (RESEARCH AND DEVELOPMENT)

4.8.1 Status of Bar Codes in UK Transfusion Services

Mr Moores reminded the Committee of the limitations of Codabar as currently used in all RTC's. Despite these limitations, the use of concatenated reading was a vital factor in the correct labelling of blood products.

The ISBT is now considering a move away from Codabar to Code 128. This code is an internationally recognised code developed by AIM (Automated Information Manufacturers). ISBT is attempting to define codes to be used by Blood Transfusion, but at present the ability to provide for concatenated reading is proving difficult. It was also pointed out that to transfer from Codabar would be both difficult and very costly. Mr Moores agreed to keep members briefed of developments. MM

4.8.2 Update on Blood Bank Computer Developments

Mr Moores reported that as an interim measure, the Stride system would be transferred onto more modern hardware. This project was expected to last 3 months. As part of the system, all Centres had now nominated their representatives for consultation. Many of these had already been consulted.

4.8.3 Laboratory Computing

GRO-C

GRO-C

Mr Moores reported that as a result of a conversation with Mr Bruce, it was clear that the procedures for the introduction of amended software for laboratory testing equipment were not secure. This had lead to the incorrect interpretation of results on at least one occasion.

Mr Moores recommended that a far tighter procedure for such amendments be set up. **The MSC strongly supported these recommendations and noted that this message had been conveyed formally to all Centres QA Managers.** ALL

Professor Cash thanked Mr Moores on behalf of the members.

4.9 PRODUCT SERVICES DEPARTMENT

4.9.1 Compendium of Product Information

Dr Stewart apologised to members that the compendium had not yet been distributed. Distribution is expected in the near future.

1993/94 Edition

Dr Stewart is considering the membership of a team to update the data sheets and will advise the MSC of his proposals. RS

4.9.2. Report on Pharmacokinetic Study with Factor VIII Concentrates

Dr Stewart informed members that a final report of the study is due from Inveresk Clinical Research shortly.

4.9.3 Clinical Trial Status Report

Members noted the updated version of the clinical trial status report.

4.9.4. Potential Demand for IVIgG: Use in Bone Marrow Transplant Recipient

Members noted that Dr I Franklin (Royal Infirmary, Glasgow) has intimated that he anticipated the use of 1.2kg of IVIgG per annum in BMT recipients.

4.9.5 Rubella Immunoglobulin

Dr Stewart proposed that in view of the low demand for Rubella IgG, and the large batches which have to be made, the manufacture of Rubella IgG should cease. **Members agreed to this proposal.** Dr Perry suggested that increased doses of normal IgG could be used as an alternative to Rubella Immunoglobulin. Dr Stewart agreed to explore the rubella antibody content of normal IgG with a view to calculating the appropriate dose. RS

4.9.6 Hepatitis B Immunoglobulin

i) *Demand for Intravenous Hepatitis B Immunoglobulin, and Hyperimmune Plasma Collection*

Members noted that the hepatitis B plasma collection target would need to be increased from 70kg to 170kg if the use of intensive plasmapheresis schedules are not adopted for the collection of this material from a small number of boosted high titre donors. Dr Stewart agreed to provide a breakdown of the hepatitis B collection target for RTC, in International Units. RS

ii) *Intramuscular Hepatitis B: Needlestick Injury Use*

Members noted the correspondence for Dr Mitchell. Members supported Dr Mitchell's proposal of extending the availability of anti-hepatitis B immunoglobulin in the West.

4.9.7 Clinical Trial of IVIgG in Asthma

Dr Stewart updated members. Members noted that a placebo controlled trial of IVIgG in asthma is currently being discussed with Dr Petrie (Cameron Hospital, Fife) and Dr Franklin (Raigmore Hospital, Inverness).

4.9.8 Clinical Trial of IVIgG in Chronic Inflammatory Demyelinating Polyneuropathy

Members noted that a placebo controlled trial of IVIgG in CIDP is currently being discussed with Dr Willison (Southern General Hospital, Glasgow). It is likely that this study will become multi-centre.

4.9.9. Clinical Trial of IVIgG in Bone Marrow Transplant Recipients

Members noted that a trial of IVIgG in prevention of infection in BMT recipients is currently being discussed with Dr Franklin (Royal Infirmary, Glasgow). There is a possibility that this trial may not be necessary. Dr Stewart will brief colleagues on future developments. RS

4.9.10 Clinical Trial of IVIgG in Vasculitis Associated with Rheumatoid Arthritis

Members noted that a trial of IVIgG in vasculitis associated with rheumatoid arthritis is about to commence with Dr Jobhanputra and Professor Nuki of the Western General Hospital in Edinburgh. It is probable that this trial will become multi-centre.

4.9.11 Clinical Trials of Fibrin Sealant

Members noted that the trials of fibrin sealant have been postponed until there is material available from HCV screened plasma. It is anticipated that this will be available in April 1993.

4.10 DONATION PROCESSING

No items.

5.0 MISCELLANEOUS NEW ITEMS

5.1 Report on Inverness Major Incident Exercise

Members noted that a major incident exercise was held in Inverness on 18 November 1992 and that the outcomes were satisfactory. It was agreed that the major incident exercise should be held annually and Dr Galea agreed to take on the responsibility. GG

5.2 Bi-annual Report of the MSC

Dr Prowse requested that in items 10, 11 and 12 'CVP' should be changed to 'PDG'. RS

The report was otherwise accepted by members and it was recommended to be taken to the SNBTS Management Board.

6.0 ANY OTHER BUSINESS

6.1 Working Standards for Virological Safety Testing of Blood

The microbiology subgroup of the QA group are concemed about working standards for virology kits. Initially the primary interest is in standards for HIV-1/HIV-2 and HCV. Members noted that the likely cost of this is estimated at £25,000 - £30,000 per annum, as quoted by NIBSC. **The members gave their full support for the proposals, but were anxious for costs to be reduced if possible.**

7.0 FUTURE MEETINGS

The next PES meeting will be on 31 August.

The next MSC meeting will be on 11 and 12 May 1993. Professor Cash proposed that the August meeting be moved to 4 August, to last for one day only. Members agreed.

Professor Cash thanked members for their valued contribution and the meeting closed at 4.00 pm on 10 March, having closed at 4.30 pm on 9 March.