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FOR 7/82

CONFIDENTIAL

MEETING OF THE SNBTS MEDICAL & SCIENTIFIC COMMITTEE
16 MAY 1991, SNBTS HEADQUARTERS,
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 W McClelland
Dr C V Prowse
Dr R R C Stewart (Secretary)

In Attendance: Dr A Robinson

1. **APOLOGIES**

No apologies were received.

2. **MINUTES OF THE PREVIOUS MEETING OF THE MEDICAL & SCIENTIFIC COMMITTEE HELD ON 19 FEBRUARY 1991**

2.1 **Comments**

Dr Whitrow commented that item 3.5 Section D iv - 'I thought that the new schedule would be introduced with the new edition of the donor selection A-Z and that it was anticipated in about 12 months time, ie the action related to the book issue rather than the time per se.' The minute was to be unchanged.

Dr Perry pointed out that item 3.12 delete 'to the MI satisfaction' this was accepted.

Professor Cash item 3.12 delete '31 March 1991' and insert 'in the near future'.

Item 3.7 The following was inadvertently omitted and should be added to the final paragraph 'Members of the Committee approved Mr Bruce's proposals'. Both points were accepted.

ACTION

3. MATTERS ARISING FROM THE PREVIOUS MINUTES OF 19 FEBRUARY

3.1 Blood Donation Programme (Standing Item)

3.1 a UK Standing Committee Red Book Volume II

The Committee agreed that Dr Galea and Mrs Thornton should serve on Dr Wagstaff's UK Standing Committee on Donor Selection Criteria. The Committee agreed with the proposal that Dr Mitchell replace Professor Cash who will now head up a new UK BTS Sub Committee on Blood Components.

3.1 b AIDS Leaflet

Dr McClelland reported on a meeting of a group established on behalf of the Department of Health Expert Advisory Committee on AIDS to review the AIDS leaflet for blood donors, which he Chaired. Professor Cash suggested that there was a clear need for harmony and timing of leaflet changes between the SNBTS and the NBTS. Members of the MSC were asked to note that the Scottish Office do not make any comment on SNBTS AIDS leaflets unlike the Department of Health in England with regard to NBTS leaflets.

Dr McClelland raised the following specific points. The reference to 1977 in relation to item on 'men who had sex with another man' should remain in. It was also agreed by the Committee that the life time exclusion of known intravenous drug abusers should continue. It was felt that it could not accept point 6 of the appendix 3.1b (Men and women who had had sex any time since 1977 with a member of the opposite sex who had resided in a area with a high prevalence of AIDS). Dr McClelland's Group felt it would be difficult to define what was a high prevalence area. Concern was expressed that the mentioning of Africa in particular may be viewed as having racist overtones and the Group were further concerned that this fact may be emphasised by including the phrase 'Persons of any race'. It was suggested that a more appropriate phase may be 'Persons of any ethnic origin'.

Dr Perry suggested that the wording should be changed from 'Haemophiliacs' to 'Persons with Haemophilia'. The Group noted that the time limit for persons giving blood after admitting to having sex with a prostitute had been increased to 12 months. The Group noted that there were no data at present to demonstrate the association between other STD's and HIV however, it was agreed that the 12 month exclusion of persons who have had a STD adopted by the FDA was considered sensible.

Once the Committee had discussed the new information presented it was agreed that there was no likelihood in the next 6 months of the UK NBTS and Department of Health agreeing the revision of the AIDS leaflet. Professor Cash therefore asked the Committee whether the SNBTS should await the emergence of the UK BTS position. **It was agreed that the SNBTS should await the emergence of the UK BTS position.**

Professor Cash thanked Dr McClelland for briefing the MSC on the progress.

3.2 **HCV Donation Testing**

(a) **RTC Screening Start Date**

The Committee noted that the Newcastle RTC had unilaterally started the HCV testing. In response to this development, Dr Gunson as Chairman of the Advisory Committee on Transfusion Transmitted Diseases, had proposed that four Centres would take part in a full scale screening evaluation of second generation Ortho and Abbott kits. This proposal had the support of DOH. The Abbott kit was to be used in Newcastle and Glasgow while the Ortho kit was to be used in Leeds and Liverpool. It had been suggested that the 4 centre full scale evaluation should run beyond mid July 1991, through to September, and that this period be used to acquire additional information on confirmatory testing.

In relation to this second generation study the Scottish Centre (Glasgow) would send samples to Dr Follett. It was noted that DOH has provided funds for the 3 NBTS Centres and Professor Cash had advised Dr Gunson that the SNBTS could self-fund. The report on the screening study would be available in early August.

The best estimate for the commencement of routine testing currently is 1 September 1991.

3.2 (b) **Confirmation Testing**

(i) The Committee noted that the Unit General Manager of Ruchill had intimated to Mr McIntosh that they would be willing to allow Dr Follett to operate as the SNBTS confirmatory tester. It was noted that within the next three months the Unit General Manager would meet with Mr McIntosh to agree the contractual arrangements. DMcI

Professor Cash agreed to notify members of the Group on Dr Follett's plans to commence the programme. JDC

(ii) **PCR/HCV**

Dr Yap had recently appointed a molecular biologist with experience of PCR/HIV. It was agreed that the SNBTS are committed to include the PCR for HCV but that this should be subject to regular review.

Dr Whitrow raised the point that the computing unit must become involved as DOBBIN must be able to flag a donor that is acceptable for plasma donation only, due to their HCV status. This was agreed. RS

3.2 (c) **Acceptance of Plasma for Fractionation and Donor Management**

The Committee discussed the document prepared by Dr Gunson. Dr McClelland was concerned that there was a lack of logic in testing donors for anti-HCV and then ALT if the anti-HCV was positive. He pointed out that it was possible to have a false positive for anti-HCV who will then be tested for ALT and this will be found to be elevated. This donor would then be excluded while an anti-HCV negative donor with a high ALT would not have been tested and therefore would not be excluded.

Professor Cash agreed there was a problem and agreed to refer back to Dr Gunson. JDC

Dr McClelland expressed a further concern that Dr Gunson's leaflet while covering all the major points was unworkable. He stated that a much simplified version would be required for operation. Professor Cash advised that the complexity of Dr Gunson's table arose out of a desire to let Directors see that all possibilities had been considered. He was certain the important point made by Dr McClelland would emerge as the confirmatory testing process was clarified.

The Committee agreed that the Director of the Virology Reference Centre should unequivocally state a positive and negative on the report form sent back to the SNBTS.

Dr Perry pointed out that NIBSC would prefer that anti-HCV donations should be excluded from plasma pools. They would be testing pools and final products for presence of HCV. He thinks that it is essential that this point be discussed with them immediately to ensure that the position can be clarified. JDC

Dr McClelland suggested that even with several anti-HCV positive individual units included in a plasma donation neither the pool or the final product would likely to show up positive assay; positive donations would be diluted.

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

3.3 a The Committee noted the insurance scheme which had been arranged by Mr McIntosh.

3.3 b **Crawford Report**

Dr Crawford joined the group at this point.

Dr Crawford spoke to his paper. Dr McClelland suggested that as much of this document was related to costing, it was more appropriate that it be discussed by the Board. It was agreed that in general terms that would be a more appropriate forum, however in the circumstances it was felt appropriate to continue.

Dr McClelland pointed out that Dr Yap had looked at the costings and suggested that the capital costs of the West could be halved and that single items of equipment could be bought in the first instance.

The Committee agreed that Dr Crawford should have visited the other Centres and consulted with senior members in Aberdeen and Edinburgh.

It was agreed that for costing purposes a uniform cost of £8 plus VAT per test should be set for the country. It was noted that there were no claims for clerical support from any other region other than the West of Scotland. Dr Crawford had said that the Co-ordinating Group in 1988 stated that only the West would be significantly financed. However Dr Yap had produced a note on the extra laboratory costs that the South East would require. Professor Cash suggested that if the project was to proceed, it would be necessary for contacts with the other RTC's to be made, to determine exactly what administrative and clerical support they might require for the bone marrow transplant donor programme.

Dr Crawford pointed out that his costings assumed that major printing costs would be supported by Mrs Thornton's budget. It did not appear that Mrs Thornton had been consulted. Specific items in the report were:

- Confidentiality - this is accepted. Private patients point accepted, foreign patients point accepted, life assurance accepted however it should be noted that the SNBTS do not wish to enforce compliance. Documentary of evidence however should be maintained that the SNBTS has supplied the appropriate letter to the donor. It was noted that the policy had been arranged by Mr McIntosh.
- Minimum age - it was previously agreed that bone marrow donors should be whole blood donors who have donated on at least three occasions with no problems. It was agreed that this policy should be maintained and therefore there was no point in typing a 14 year old.
- Nolan volunteers - This point was accepted, however the Committee agreed that regular blood donors who fit BTS criteria should be encouraged to switch to the NBTS Bone Marrow Panel.
- Use of donors - agreed.
- Upper age limit agreed.
- Regulatory authority - agreed.
- Ethical code of transplant centres - this was accepted and it was noted that this was a code currently used in England and Wales.
- Members of the Committee requested that they be shown the complete package of flow charts, primary leaflet and secondary document for donor. Also, they would require notification of the procedures in each Centre, however this did not need to go to the level of laboratory protocol. It was also agreed that detailed programme up to the launch date was required.
- Data transfer - this point was accepted and also it was agreed that it was possible to have a standard letter for use throughout the SNBTS and that the Advisory Group should supply suggested texts to the MSC for consideration.

It was noted that this is in fact a bone marrow and platelet panel not an appeal, and all the Committee felt that the title should be changed to reflect this.

It was agreed that the package should be pulled together as soon as possible. If this was at all possible it should be presented to the Board meeting on 11 June 1991, but if not it should come back to the MSC on 14 August 1991.

The members agreed the report was disappointing and as the Bone Marrow Donor Panel might rapidly be entering implementation phase it was felt that the Co-ordinator of the Programme should pass over to a Regional Transfusion Director and Dr Urbaniak volunteered to act as Co-ordinator.

It was agreed that Professor Cash should write to Dr Crawford thanking him for bringing the programme to this stage and requesting him to send all the relevant papers to Dr Urbaniak. JDC

Professor Cash suggested that the Group continue with Dr Urbaniak, Dr Gillon, Dr Galea and Mrs Thornton and that Dr Urbaniak and Dr Mitchell should discuss the Western Region representative. This was agreed. SJU/ RM

Dr Urbaniak also agreed to review the costings and produce a standardised list for cost throughout the SNBTS. It was also agreed that the launch date should be determined by Dr Urbaniak in consultation with Mrs Thornton. It was felt that the package should be presented to the next MSC and therefore the launch date would probably be after that. SJU

Dr Urbaniak agreed to try to have a draft timetable available in time for the Board meeting on 6 June. It was agreed that all members of the MSC should review the package so that corporate responsibility was maintained.

3.4 **Inspection of Private Hospital Blood Banks**

Professor Cash asked the members of the Committee if they found Dr Mitchell's document 'Procedures for Inspection of Premises in Private Hospital Blood Banks' an acceptable document. Dr McClelland felt that the name was inappropriate and suggested that 'premises in' be deleted from it. **This was agreed.**

The Committee agreed that the document was acceptable and it was further agreed that Drs Mitchell and McClelland should liaise to decide which publications should be used to define the standards the Blood Bank would have to comply with, to conform to UK Good Blood Banking Practices. RM/ DBLMcC

Professor Cash thanked Dr Mitchell for preparing the document. **Professor Cash further agreed to write a formal letter to all Transfusion Directors pointing out that this was the new agreed system for inspecting private hospital blood banks. This would not take place until he had received the final copy (with the proposed additions) from Dr Mitchell.** JDC/ RM

3.4.1 **Laboratory Accreditation**

It was noted that Professor Cash had discussed this point with Dr Lilleyman who had confirmed that the Royal College of Pathologists had not yet given consideration to RTC's. **It was agreed that this item should be taken off the agenda.**

3.5 **Quality Assurance Group (Standing Item)**

The short update briefing note prepared by Martin Bruce was noted and Committee extended their thanks to Mr Bruce for preparing the update. It was noted that an English QA Managers group had been set up and that the SNBTS would have observer status on this group.

3.6 **Adverse Event Reporting**

A draft SOP prepared by Drs Cuthbertson and Stewart was discussed. Subject to minor modifications suggested by Dr McClelland it was agreed this standard operating procedure could be implemented from 1 September 1991. It was pointed out that general practitioners might be unaware of this system being in place and Professor Cash suggested that Bruce Cuthbertson and Robert Stewart give some consideration to how they could be informed of this and how the system would operate. RS

Professor Cash confirmed he would formally send out the final document when Dr Stewart had lodged this with him. RS/ JDC

Professor Cash pointed out that in such situations in which the National Medical and Scientific Director's opinion was required, the deputy to the National Medical and Scientific Director had been the Director of the Edinburgh Centre and whenever he was unavailable the deputy then became the consultant on call in the South East. He asked whether this would remain and was acceptable to members of the MSC. **It was agreed that this was so.**

3.7 **Manufacturers Licences**

It was noted that all 5 RTC applications for manufacturer's licences had been timeously submitted and the Committee thanked Mr Bruce for his efforts and colleagues in the West of Scotland for the extensive typing work involved. The Chairman was asked to write formally expressing the Committee's thanks to Mr Bruce. JDC

It was agreed that Professor Cash should meet with the Transfusion Directors in Aberdeen, Inverness and Dundee to discuss the line management position in those Centres. This was to ensure that the relationship between QA Manager and Production Manager would be acceptable. JDC/ WW/ SJU/ EB

4. **RTC PLATELET USE**

It was noted that Dr Stewart had completed his option appraisal but that full financial costings were not available at this time. **This item was deferred to the next meeting and it was agreed that Drs Stewart and Murphy should attend the MSC to present the paper.**

It was agreed that Dr Stewart and Professor Cash should ensure that Mr Francis is aware of the deadline for the financial side of the package. It was further agreed that the financial arrangement analysis should be sent early to the Regions to allow them to consider this in their local arrangements. RS/ JDC RS

5. **SPPS CLINICAL USE: NEUROSURGERY**

Professor Cash thanked Dr Mitchell for bringing to his attention the letter. The Committee agreed that the Regional Transfusion Directors should check with their local neurosurgical units to see if there was a change in practice which is likely to increase demand throughout the NHS in Scotland. **It was agreed that Transfusion Directors should inform Dr Mitchell of the outcome of these investigations and Dr Mitchell should decide whether the item is to come back on to the agenda of the MSC.** RTDs

6. **MALARIAL RESEARCH IN EDINBURGH UNIVERSITY**

The Committee noted that the West of Scotland RTC could not supply Professor Walliker with the material they requested due to their other commitments. **It was agreed that Dr Mitchell should inform Professor Walliker and say that he has raised the issue with his colleagues and that Dr McClelland is making strenuous efforts to assist and has approached the other Transfusion Directors to see if they may be able to help also.** Professor Cash requested that the Transfusion Directors make all efforts possible as this was a world leading group in the field. RM

7. **HLA REAGENTS SUPPLY**

1. The Committee noted the correspondence presented.

2. The Committee further noted that Professor Cash is monitoring the position and will keep the Committee informed of developments. If Professor Cash has not heard from Dr Evans in a month he will follow it up. JDC

3. The SNBTS should not take any action to make a special SNBTS plate at this stage but should continue to send material to UKTS.

8. **BSI REVISION OF BS 5736**

This was noted and the Committee thanked Dr Urbaniak for keeping the group briefed. The Directors noted that they had no further comment and the item was to be removed from the agenda.

9. **NATIONAL DONOR DEFERRAL REGISTER**

Professor Cash stated that the paper produced by Mr Moores had been received too late to be circulated to members in advance of the meeting. He proposed that the paper be given to Drs Galea and Gillon and Mrs Thornton to consider from the donor side. GG/ JG/ MT
Dr McClelland stated that there were 3 particular points he felt that had to be discussed. 1. Was the donor deferral register workable; 2. Positive donor identification, and 3. The QA arrangements which were in place to ensure that the flagging of deferred donors was working. Dr McClelland stated that in addition to ensuring that they had a system which worked it was essential that the SNBTS was seen to be making efforts in this area.

10. **DONOR SESSION STAFFING GROUP**

It was noted that Professor Cash, Dr Urbaniak and Mrs Thornton thought that it was a major advance that someone would be appointed as managerially in charge of each donor session. It was noted that the paper prepared by the group was a first attempt and they were thanked for this. It was further noted that the paper has the support of the Nurses Group and Donor Services Manager group. Dr McClelland was concerned that it did not allow the running of sessions without doctors in attendance, and that this option should be left open.

Professor Cash pointed out that it would allow session to be held without doctors on the premises but within 5 minutes of being present in case they were needed for resuscitation. It was considered that this was a valuable move in the right direction. **It was agreed that the process should undergo regular reviewal, and at some time in the future it may be considered appropriate to pilot a session without a doctor in attendance at all.**

It was agreed that Dr McClelland should check the CPR Guidelines in the Royal Infirmary of Edinburgh and see if they come up with a better wording which could be used rather than the 5 minutes. Professor Cash thanked the group for their comments and valued discussion. He agreed to now circulate the document formally to the Regional Transfusion Directors when Dr McClelland had briefed him on his local CPR Guidelines. JDC/ BMcC

11. **UK BTS RECOMMENDATION FOR THE USE OF ANTI-D IMMUNOGLOBULIN**

Dr Urbaniak presented this to the Committee for their formal approval and said that if there were any comments he would relay them back to Douglas Lee. The Directors thanked Dr Urbaniak and agreed that they had no material comments on the document which they warmly welcomed. It was noted that the Prescribers Journal were willing to publish the document in full and this interesting development in information dissemination was appreciated by the Committee.

12. **NATIONAL SCIENCE LABORATORY (Standing Item)**

It was noted that Dr Prowse had no report to present at this meeting.

13. **MEDICAL AUDIT COMMITTEE (Standing Item)**

Dr McClelland briefly reported that they had completed 3 audit applications which had gone into the Audit Sub-Committee of CRAG. He apologised for not circulating these to the Transfusion Directors in advance and pointed out that because of tight time deadlines this had not been possible. It was noted that funding for the appointment of a Clinical Audit Co-ordinator for the SNBTS had been agreed.

14. **NATIONAL REAGENTS PROGRAMME (Standing Item)**

The update briefing note prepared by the Reagents Manager Mr Bruce was noted. Mr Bruce was thanked for preparing this once again for the group.

15. **BLOOD COLLECTION PROGRAMME (Standing Item)**

Dr Galea presented the first draft of phase 1 of the National Donor Health Check Guidelines. It was noted that this was a continuing development programme and the other phases would relate to new donors.

15.1 **Donor Health Check Leaflet (DHC1)**

This had been shown to the Donor Consultants, to the Central Legal Office and had been tested by Hoffman Research and it was noted that it was being well received by donors.

Professor Cash proposed that the group approved the introduction of donor health check (DHC1) for routine use as soon as possible. This was agreed.

Dr Brookes pointed out that on item 4 of DHC1 'ever' should have been 'a large blue bar' in the same way as in the past 6 months etc. Dr Galea and Mrs Thornton agreed to this and said that at the first revision, this would be altered. The question relating to 'ever' would would be included underneath the bar. GG/MT

There was discussion about whether fits should be included after epilepsy, however it was agreed at this stage it should be left in. Dr McClelland pointed out that it may be difficult currently to define Western Europe and this would be given consideration at the next review. Dr Galea pointed out that in response to comments at the previous MSC meeting that one particular AIDS category had been separated from the rest, this had been revised and all categories were now included together in a single list. It was noted that the next review consideration would be given to changing from this list to series of questions based on risk groups. **DHC1 was accepted by the Committee.** GG/MT

15.2 **Donor Consent Form**

The proposed new wording of the donor consent form was noted and agreed.

It was noted that Dr Gillon's letter suggested that there had been an increase in self exclusion which correlated well with the increase in number of donors found to be anti-HIV positive. Dr Galea reported Dr Gillon's proposition that this should be looked at nationally. Professor Cash said that it

would need good research and that information from a couple of centres may not answer the question.

15.3 **Health Check for New Donors**

The Health Check for new donors leaflet was discussed. It was noted that this required that the new donor should tick boxes to confirm that they do not fall into the deferred categories. Dr Galea confirmed that on a basis of safety, they were recommending to the MSC that new donors should be given a more detailed health check and that a simpler version would be fully developed for repeat donors.

Professor Cash enquired whether they would consider it appropriate to have a full, more complex, health check for all donors. Dr Galea agreed that this would be appropriate however he did not think it would currently be logistically feasible within the SNBTS and suggested that it would be best to start with new donors. Once more experience with the system has been gained, it will evolve towards all donors. **It was agreed that it was appropriate to consider that, in the long term, self completion forms would be used for all donors. The Committee agreed this programme in principle.**

It was agreed that the donor consent form should specify which version of the donor health check he has read, e.g. it should currently actually mention form DHC1.

15.4 **Basic Minimum Standard Questions**

It was agreed that these questions were adequate, however it was pointed out that question 3 may be complex because of the negative question, i.e. have you been keeping well, not attending your doctor or hospital or taking any medication?

15.5 **Health Information for Donors (HI2)**

Leaflet entitled Health Information for Blood Donors (HI2). This was discussed and agreed in principle. It was pointed out that in section 'Do not donate' should read '(contraceptive pill acceptable)'. Mrs Thornton advised the committee that this leaflet was to be included in the pack given to new donors but would also

be available to all donors at sessions as a stand alone item.

15.6 **Health Information for Blood Donors (HIl)**

It was noted that this would be on the back of the donor call up card or letter. **This was approved by the Committee.**

15.7 **'Thank you for Sharing your Health'**

Layout and content of this leaflet was discussed. Professor Cash pointed out that in 'Hepatitis B' the fact that the blood was tested for this should be stated. This was agreed. Mrs Thornton advised the Committee that this leaflet had gone down well with donors and they had also been approved by the CLO. There was positive feedback from the donors and they felt that the leaflet was useful as it showed the concern not only for the patients but also for the safety of the donors. MT

Donors had suggested that it should include the statement that you cannot catch AIDS from giving blood. **It was agreed tha this would be valuable to add this in.** MT

It was noted that this leaflet 'Thank you for sharing your health' would be introduced after the introduction of hepatitis C testing. **The Committee supported the development of the whole package and agreed that it should go ahead with the current age groups and not be held up awaiting the publication of the new UK BTS agreed Guidelines.**

Professor Cash expressed the gratitude of the Committee to Dr Galea and Mrs Thornton for their excellent work. He requested that they produce a single sheet which should be circulated to the Directors detailing the implementation plan for the various leaflets. **This was agreed.** GG/ MT

16. **TEAR DOWN PACKS**

It was agreed that Dr Perry should prepare a paper for the next meeting of the MSC on this topic. Dr Perry advised the Committee that Tuta had visited and had discussed the possible introduction of tear down packs in the UK and had proposed they could supply machines and packs to the SNBTS. Dr Perry reported to the group that BPL was now very interested in this project and that tear down packs were in semi routine use in Australia. RJP

17. **ANY OTHER BUSINESS**

Item (a) Anti-D Trial - Dr Mitchell expressed his concern that clinicians may learn of the trial and use anti-D immunoglobulin antenatally, routinely.
Dr Urbaniak replied that the agreed national policy was that routine use of antenatal anti-D would only materialise if the trial showed advantage to patient.

Item (b) Professor Cash asked the Committee if they knew of any plans to audit Kleihauer testing. Dr McClelland replied that it was one of the audit proposals currently under consideration by CRAG.

Item c -Annual Report from Chairpersons of Groups reporting to the MSC. Professor Cash proposed that these Chairpersons be requested to produce annual reports of how their unit have performed and of achievements versus the targets which have been set.
Professor Cash agreed to contact the relevant Chairpersons. JDC

18. Professor Cash thanked the Committee for their efforts over the two days and asked them to note that the next meeting was scheduled for 14 & 15 August 1991.