

0002

## CONFIDENTIAL

MINUTES OF THE MEDICAL & SCIENTIFIC COMMITTEE, HELD AT  
HEADQUARTERS, ELLEN'S GLEN, ON TUESDAY 19 FEBRUARY 1991

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

In attendance: Mrs S Shearer

1. APOLOGIES

Apologies were intimated on behalf of Dr Angela Robinson.

2. MINUTES OF THE MEDICAL & SCIENTIFIC COMMITTEE HELD ON 6  
NOVEMBER 1990 AT HEADQUARTERS, ELLEN'S GLEN

The comments, circulated with the Agenda, from Drs Whitrow, Urbaniak and McClelland were noted.

It was agreed that Dr McClelland's comments on Item 10.ii Flow Chart be adopted as the correct record:

"It had been agreed that Dr Mitchell would convene a meeting, which would involve the medical person and the laboratory head responsible for virological testing of donations from each Centre, the sole purpose of this meeting being to establish a firm and binding agreement to a general flow chart covering Hepatitis B, HIV 1 and 2, and Hepatitis C. Following this, an audit into the compliance with these procedures would be conducted in the Centres."

The Committee then approved the Minutes as a correct record of the meeting on 6 November 1990.

### 3. MATTERS ARISING

#### 3.1. Item 4.i: Medical Audit Committee

The Chairman invited Dr McClelland to comment on his Report (previously circulated).

Dr McClelland tabled a Paper entitled "Proposed Audit Project: SNBTS National Audit Committee". A copy is attached to these Minutes.

He then outlined the three projects, detailed in his Paper, that the Group had identified as a starting point.

Further to Professor Cash's letter of 6 February 1991, previously circulated, it was agreed that it was necessary to clarify and define the role of the Medical Consultant in the RTC.

(JDC)

It was noted by the Committee that the next deadline was 26 March 1991 for applications to be considered at the May 1991 CRAG meeting.

Dr Mitchell raised the question of overlap in general between this Group and Mrs Thornton/Dr Galea's Group with regard to Project 1 for example and the Committee agreed that close co-ordination was essential. **The following was agreed:**

- a) The Medical Audit Group will issue copies of applications to CRAG to MSC Members in advance with a seven day deadline for comments.

BMCC

- b) Individual Medical Audit Group members to liaise closely with their respective Directors.

- c) The Minutes of the Medical Audit Group to be circulated to the RTDs.

(BMCC)

It was noted that Dr McClelland is preparing a list of SNBTS activities which include a significant amount of medical audit.

Professor Cash commented that there were two major issues to be addressed by Medical Audit Group. These are:

- a) The extent of Donor Selection Auditing
- b) Monitoring of clinical use of blood

With regard to (a), the Committee agreed that the National Quality Assurance Group would require to liaise carefully with the Medical Audit Group.

JDC/BMcC

Dr Perry pointed out that, in principle, the Medicines Inspectors were not interested in the details of guidelines, but were concerned that, in keeping with BS5750, appropriate mechanisms were in place.

After extensive discussion on the role of the Medical Audit Group, the Committee agreed to accept, in principle, the Report prepared by Dr McClelland. Dr Mitchell raised the matter of confidentiality and pointed out that neither patients nor staff should be identified. He was assured by Dr McClelland that the Medical Audit Group was in possession of the Confidentiality Guidelines and would ensure that they were adhered to.

Professor Cash invited Dr Galea to join the meeting at this point.

### 3.2 Item 5: Blood Collection Programme

#### 5.1 (a) Upper Age Limit

The previously circulated correspondence from Mairi Thornton, dated 6 December 1990, was noted by the Committee.

Dr Whitrow stated that, in his Region, he would not be measuring blood pressure but would be asking donors to certify that they had discussed blood donation with their GP and the GP had agreed that it was acceptable for them to continue to give blood.

Professor Cash requested Dr Whitrow liaise with the Central Legal Office on this matter to receive legal guidance on whether this was an appropriate procedure.

WW

### 3.3 Siii (b): UK Standing Committee: 'Red Book': Vol 1

The Committee noted the comments on the Agenda

regarding this matter. Professor Cash stated that the Group had not yet met but the matter was in hand.

3.4 Sii (c): Donor Counselling: HCV Donation Testing

The Committee examined Dr Gillon's final draft document, which had been previously circulated and agreed it was excellent. The Committee proposed and agreed that the latter pages be used as Guidelines in leaflet form for use by the RTCs.

In the light of national events, it was agreed no "Look Back" should be introduced at present. This led Dr Galea to comment that the wording of the last Question on page 9 would need to be altered accordingly. This was agreed.

3.5d Item 17: A-Z Donor Selection Criteria Guidelines

- i. The Committee agreed to homologate the action taken by Professor Cash to adopt the recent A-Z Guidelines nationally with immediate effect.

Dr Whitrow expressed his concern that the A to Z guidelines had been issued as an SOP. He stated that guidelines are not SOPs but that local SOPs should be generated from national guidelines.

Dr McClelland asked whether these were Guidelines or an SOP. The Chairman replied that these were Guidelines and the letters SOP should not appear on the document. Dr Galea noted this.

- ii. The Committee thanked Dr Galea and Dr Brookes for their work on this document.
- iii. The Committee noted that an annual review of these Scottish A-Z Guidelines would take place and the MSC would have the opportunity to review any proposed modifications. Dr Galea was to advise on the action date of this review in line with UK Committee meeting next year. This he agreed to do. All comments from RTC staff, in the intervening period are most welcome, and are to be forwarded to Dr Galea for collation.

The Committee also agreed that (Scottish) National Guidelines - as documents of importance - such as the A-Z should have the following:

- a) a more formal issue/recall of previous versions policy

b) a cover clearly stating date of issue and date of next review

JG

c) a different coloured cover each year

d) a foreword of authorization of use by the NMSD

e) each RTC be responsible for withdrawal of outdated documents within its own Region

In connection with (e) Dr Whitrow expressed the wish to be provided with adequate replacement copies each year due to the very limited resources in his Region.

- 3.5 d v. Dr Mitchell was invited to explain the latest Malaria Flow Chart. The 3 main differences between the chart and the existing Guidelines were then highlighted by Dr Galea.

Professor Cash stated that these variations would not require to be implemented any sooner than 12 months from now. Dr Mitchell responded that West BTS intended to implement within 6 months, whereupon it was decided by the Committee to leave the timing of this, within the 12 month schedule, to the discretion of each RTD.

The Committee agreed that Dr Mitchell and Mr Barr be formally thanked for their efforts.

JDC

3.5 e Further Update

a) Health Check

It was noted that the South East was the only Centre which currently does not include the AIDS "High risk categories" in the call up letter. Professor Cash expressed his concern that one Region was out of line with the others. It was agreed that Dr Galea liaise with Mrs Thornton to ensure that AIDS call-up categories were included in all RTC letters.

JDC/GG

Dr Galea tabled the proposed document (previously circulated) on Health Checks. He also presented galley proofs of the Health

Check (2 sides A4) for examination and comment by the Committee. He stated that the wording used on the Health Check had been arrived at after Mairi Thornton had consulted experts in the field of communication. The Committee requested that it have sight of the documentary evidence of that consultation at the next meeting of the MSC as the Committee was most interested to know the nature and content of the advice received.

RS/MT

Dr McClelland asked, for example, why Question 18 was separate. Had this been as a result of the sociologist's advice?

The Committee requested Dr Galea report back the result of the discussion on this topic to Mairi Thornton highlighting the following points:

GG

- a) Await new UK BTS AIDS Criteria
- b) Dr Galea should attempt to improve the wording in the light of comments from the Committee
- c) Question 18 - clarify
- d) Professor Cash and Dr McClelland expressed the view that they would like to see the dossier of documents (both in draft typed and final form) so that they can examine them from the perspective of a donor. It was agreed that it would be of value if these documents were circulated to the Committee.
- e) Question of signing/Box ticking by donor

c) Leaflet: "Thankyou for Sharing Your Health..."  
(Donor Screening Leaflet)

Dr Galea explained how this had been arrived at and also circulated galley proofs of this document.

Dr McClelland and Dr Brookes, who both had comments on the text, agreed to forward their comments to Dr Galea by 28 February 1991. ✓

BMcC/EB

Dr McClelland raised the question of the legal implications of this document. The Committee agreed to ask Mairi Thornton, through David McIntosh, to consult with the CLO, having taken on board the comments to be passed to Dr Galea.

RS/MT/DmcI

The question of a formal linkage of the Health Check to the Donor Screening Leaflet was also raised. The Committee concluded that a formal reference to the Donor Screening leaflet should not be made within the Health Check document, but that some mechanism for recording that the donor has been informed of the existence of the Donor Screening Leaflet and is aware of its contents should be devised.

RS/GG/MT

Dr Urbaniak suggested that a formal process for updating of this leaflet be introduced in the context of new tests being implemented in the future.

Dr Galea was thanked for attending the meeting at this point and the Committee adjourned for lunch.

### 3.6 Item 7: Platelet Concentrates - Bar Code Labels

The correspondence dated 15th November 1990 from Mike Moores, IT Manager, which had been previously circulated, was noted and accepted.

Martin Bruce, Reagents Manager joined the meeting at this point.

### 3.7 Rh-Testing: Blood Bag Labels

The Chairman welcomed Mr Bruce and invited him to give a brief introduction to his Report which had been previously circulated.

Mr Bruce pointed out that the date of implementation was 1 April 1992. He suggested that the UK Bar Code Committee be asked to produce separate labels for Rhesus negative and Rhesus D negative.

He pointed out that the majority of packs would be labelled Rhesus D positive or negative, but there would be a need for some which were Rhesus C,D,E negative. There was discussion on the need for re-testing at each

WM

donation and Mr Bruce expressed his conviction that it was essential to retest every unit before it is issued and not depend on archives for C and E status. Dr Urbaniak stated that this would require a lot more C and E antibody, but Mr Bruce pointed out that archive records of C and E negativity could be used to select those for re-testing.

### 3.8 Item 9: SNBTS Reagents Programme

The Chairman invited Mr Bruce to introduce his Report which had been previously circulated.

Mr Bruce pointed out that, since the Report had been produced, matters had moved on somewhat. He pointed out that National reagents were on the shelf this month. These are:

Product Available:   Anti-A  
                          Anti-B  
                          Anti-A,B

Available from 1.04.91

                          Anti-D  
                          Anti-C  
                          Anti-E  
          monoclonal Anti-Lewis A  
          monoclonal Anti-Lewis B  
                          Anti-M  
                          Anti-N  
                          Anti-A<sub>1</sub>

Professor Cash expressed his concern over the costs of NEQAS and it was suggested that Dr Mitchell write to Mr McIntosh to get this Item added to the Board Agenda.

RM

Mr Bruce was thanked for attending the meeting and left.

### 3.9 Item 10: HCV Donation Testing

#### Look Back

- i. The Committee noted the comment on the Agenda that Professor Cash has written to Dr Mettors (DOH) and Dr Mettors has responded that he comments made will be considered by his Committee ( on which Dr Mitchell and Dr Perry serve).

PLY

JR/  
PLY

ii. **Flow Chart**

Professor Cash invited Dr Mitchell to comment on the latest HCV Flow Chart (previously circulated). Dr Mitchell then explained the modifications, mainly to the ALT part, and that the next meeting of the Committee will be at the end of March 1991.

Professor Cash promised to contact members of the MSC with the outcome.

JDC

Professor Cash reported that the whole question of PCR testing was being examined nationally at present and this was still ongoing. He would report any concrete developments to the Committee as they occurred.

JDC

He also stated that he had liaised with Dr Gunson on the implementation proposals for HCV testing and at present they are as follows:

National Date of Implementation: **1 JULY 1991**

i.e. as of 0900 hours on 01/07/91, all component products in RTCs will have been HCV tested

JG please  
inform  
HB

JDC

A condition of the start date, however, will be that the blood intake has been at a "normal" level for the preceding four weeks.

3.10 Item 11: BMT Unrelated Donor Insurance Scheme

- i. The Committee noted with pleasure the previously circulated Update provided by David McIntosh.
- ii. The proposal outlined in the Agenda that "Drs Crawford, Galea and Gillon and Mrs Thornton be invited to prepare a report which will include costed implementation proposals for the next MSC meeting on 15 May 1991" was approved in principle and Professor Cash was asked to inform the Group accordingly on behalf of the Committee.

JDC

3.11 Item 12: Microbiology Reference Unit

The Committee accepted in principle the proposal outlined in the Agenda "that plans to create this Unit

in West BTS are deferred indefinitely and that Dr Follett is invited to co-ordinate this service for all SNBTS RTCs"

Professor Cash informed the Committee that he has been in contact with Dr Follett on this matter and was awaiting a costing estimate from him.

He stressed that careful consultation with the appropriate Health Board General Manager would be required to ensure that Dr Follett had a contractual obligation satisfactory to both parties. It was agreed that it would be appropriate for Mr McIntosh to undertake this and Professor Cash would liaise with Mr McIntosh accordingly.

JDC

Dr Mitchell expressed concern with regard to the 1 July 1991 deadline. Professor Cash replied that there was no option. The deadline must be met.

3.12 Item 3.12: PFC Manufacturing Licence

Professor Cash invited Dr Perry to report on the outcome of the recent Medicines Inspector's visit to PFC.

Dr Perry responded that the MI had highlighted two major and 14 minor defects, all of which have since been rectified to the M.I.'S satisfaction and it was hope that PFC will have its Manufacturing Licence by 31 March 1991. Dr Perry agreed to inform the Committee members formally of this when appropriate. Dr Perry also intimated that Drs Cuthbertson and Reid were preparing a Debrief Report for the National Quality Assurance Group on the M.I.'s visit. The Committee agreed it would be appropriate for MSC Members to receive a copy of this Report and Dr Perry agreed to co-ordinate this.

RP

3.13 Item 15: Inspection of Private Hospital Blood Banks

Professor Cash invited Dr Mitchell to report on progress to date.

Dr Mitchell replied that the matter was ongoing. He wished to examine the SHHD document from Dr McIntyre more fully and compare it to the College of Pathologists accreditation system.

RM

Professor Cash stated that it would be necessary to delineate how far the SNBTS interprets CSA contract agreements with private hospitals and he felt the matter should be raised at a future SNBTS Board meeting.

JDC

Professor Cash agreed to contact Dr John Lilleyman for clarification on the process of accreditation and report back.

JDC

4. DRAFT POLICY DOCUMENT ON THE CONDITIONS OF RTC ISSUE OF PFC PRODUCTS OUTWITH THE TERMS OF THE PRODUCT LICENCE.

Professor Cash invited Dr Stewart to comment on his Report which had been previously circulated.

Dr Stewart stressed that the Report refers to PFC products with no product licence or to licenced products used outwith the terms of the product licence.

Dr McClelland asked if the Report was transitional. Dr Stewart responded in the negative.

Dr Stewart referred, in particular, to the last paragraph of his Report and stressed the importance of documented evidence from the physician when products were issued on a named patient basis.

The Committee requested Dr Stewart write to the RTDs with clear directions as a result of his Report.

RS

It was also pointed out by Dr Stewart that he would be responsible for formal updates on Product leaflets.

It was agreed by the Committee that Professor Cash would formally issue the forms to be used so there could be no reason for confusion.

JDC

5. Collection of 500ml Donations

Professor Cash invited Dr Stewart to comment on his Report which had been previously circulated. This he did and the Committee noted and agreed with his recommendations that the volume of donation not be altered at present.

Professor Cash thanked Dr Stewart for both Reports.

Dr M McClelland left the meeting at this point.

#### 6. Tranfusion Equipment /BSI Report

Professor Cash invited Dr Urbaniak to comment on this Report which had been previously circulated. The document was discussed by the Committee which noted its contents with interest.

#### 7. Quality Assurance Group

The Committee noted the Report by Martin Bruce which had been previously circulated.

After discussion the following was decided:

- a) All RTDs (including Belfast) to receive copies of QA Group Minutes

JDC/MB

- b) The Sub-Group to liaise closely with Dr McClelland's Medical Audit Group to avoid duplication of effort

BMcC/MB

- c) On noting the planned activities of the QA Group, the MSC would wish to be assured that these activities do not unduly disturb daily running of any RTC.

- d) The QA Group should be a Standing Item on the MSC Agenda.

RS

Dr Whitrow pointed out that Mr Ian Gordon is not a QA Manager, but has responsibility for QA in Northern RTC.

Dr Perry commented that he hoped the initial audit programme would be targetted for 1991.

The Committee agreed that the need to address the issue of Q.A. staffing in Aberdeen, Dundee and Inverness was acute and the Chairman promised to raise this on behalf of the MSC as a matter of urgency with the General Manager and the SNBTS Board.

JDC

## 8. Adverse Event Reporting (PFC Products)

Professor Cash expressed concern at the present Adverse Event Reporting system, highlighting the recent event in Belfast as an example. He stated that he was meeting with Drs Stewart and Cuthbertson to examine the system.

JDC/RS/BC

Dr McClelland asked if a different form of reporting from the present system was envisaged.

Dr Stewart responded that two aspects would need to be considered:

internal (SNBTS) and the clinician

but pointed out that post marketing surveillance is very costly.

## 9. ANY OTHER BUSINESS

### 9.1 RTC's Manufacturing Licences

Dr Urbaniak and Dr Brookes expressed the wish that Martin Bruce be requested to assist personally with the documentation required for this exercise. Dr Mitchell stated that Mr Bruce had assisted the West in this exercise. The Chairman agreed to instruct Mr Bruce accordingly.

JDC/MB

### 9.2 Plasma Collection

Dr Stewart tabled a Paper on Plasma Collection Targets (copy attached to these Minutes) and explained it in detail to the Committee. The Committee noted and agreed to his recommendation on the Paper which states that targets will be issued in FR8 and FR18 and that FR8 will be (FA + FE) and FR18 will be (FB+FC+FD).

The Chairman thanked all those present for attending and closed the meeting at 1800 hours.

MSC1902/SDS