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AGREED 21st AUGUST 1991

ISSUED 300891

IN CONFIDENCE

SCOTTISH NATIONAL BLOOD TRANSFUSION SERVICE
MINUTES OF A MEETING OF THE MANAGEMENT BOARD
HELD ON 11/12TH JUNE 1991

PRESENT:
Mr D B McIntosh
Professor J D Cash
Dr W Whitrow (1)
Dr S J Urbaniak
Dr E Brookes (2)
Dr D B L McClelland (3)
Dr R Mitchell
Dr R J Perry (4)
Dr C V Prowse
Mr J N Francis (5)
Mrs M Thornton
Miss M Corrie

(1) not 3.2.2, 3.2.9, 3.2.10, 3.3.3
(2) not 3.2.2, 3.2.7, 3.2.9, 3.2.10
(3) absent for part of 3.1.1
(4) not 3.1.4, 3.1.5, 3.2.2, 3.2.9, 3.2.10, 3.3.3
(5) not 3.2.10

1.0 INTRODUCTION AND APOLOGIES FOR ABSENCE

Noted: Mrs Moira Eadie and Miss Lyndsay Small would attend on 12th June to introduce the Donor Services National Training and Development Project.

2.0 MINUTES OF THE PREVIOUS MEETING (9-10 April 1991)

Comments which had been submitted were accepted for the minutes.

3.0 NEW BUSINESS

3.1.0 ITEMS FOR DECISION

3.1.1 Budget and Development Programme 1991-92

3.1.1.1 Budgets: these were issued to the relevant Centres in advance.

3.1.1.2 Developments: Mr Francis had circulated a paper proposing the final make-up of the 1991-92 revenue development programme. It reflected the paper discussed at the April Board meeting, updated following discussions between the General Manager and Directors and included three bids from Aberdeen which had been omitted from the April document.

The funds available in April totalled £232,600 against a revised bid total of £435,000. The latter could be afforded given additional efficiency savings of £199,000 (full year effect) to which Directors had subsequently agreed.

ACTION

3.1.1.2.1 Basic level of self-funded developments £245,500: These were detailed in Appendix A to the paper, and represented the minimum 1½% efficiency savings required.

3.1.1.2.2 'To be funded' bids £435,000: This list reflected costings and requirements revised by Directors in discussion with the General Manager since April. Appendix B to the paper.

3.1.1.2.3 Dundee bid: Dr Brookes pointed out that the 0.5 A&C 2 post recorded as having been withdrawn should read 'Session Medical Officer'. She could forgo the post only if the Associate Specialist post shown as 'postponed' in Appendix A was created. She could accept an embargo to 31.03.92 but not later.

Agreed: The Medical Manpower Group to discuss the matter and make a recommendation to the Board. EMcC

3.1.1.2.4 Aberdeen: A possible further savings of one MLSO 2 post was shown in the paper as related to HCV. Dr Urbaniak explained that the 1 WTE MLSO 2 was a long-standing Aberdeen development, subsequently subsumed under anti-HCV national developments and at the previous Board meeting it was agreed that the need was independent of anti-HCV testing (although certainly affected by such testing). The post was approved by the General Manager on this basis, and steps to fill the post had commenced. A saving under anti-HCV was therefore not possible.

It was noted that the PMLSO pending vacancy was upgraded in respect of overall QA matters, and that a QA Co-ordinator (MLSO 3) and QA Officer (MLSO 2) as originally detailed in the development proposals would be required.

It was noted the NE Donor Services Review was complete and Dr Urbaniak, Mr McIntosh, Mr Francis and Mrs Thornton would consider its recommendations and options for self-funding the proposals.

Agreed: Those efficiency savings so far identified (totalling £245,500 in Appendix A) will be used to fund developments in each Centre at the Directors' discretion provided always that these developments are within the list of approved developments agreed by the Board and the total sum spent nationally on each approved development does not exceed the total agreed by the Board. This will be co-ordinated by John Francis in close consultation with colleagues and a revised Appendix A will be finalised within the next 2 weeks. JNF

3.1.1.2.5 Automated separation equipment (Appendix B)

Discussed: whether this very important project (capital £78,000, NR £20,000) should be undertaken in a single Region.

ACTION

Noted: Dr McClelland had been asked to provide the MSC with a paper on leucocyte depletion related to this equipment.

Agreed: This is a national issue and decision should await further deliberations. Professor Cash has this in hand and advised Board Members that the central issue at the present time was automation of blood processing and this matter would be addressed by Dr Stewart in his report to the MSC. JDC

Dr McClelland returned to the meeting at this point and confirmed that no equipment had yet been bought.

3.1.1.2.6 Platelet Production: deferred awaiting a financial input from Mr Francis. Dr Mitchell, whose Centre is the only one not providing an irradiated product, asked if the Service could really wait a further year. It was noted that the equipment is on a ten-month delivery. JNF

Agreed: Add a platelet irradiator to the capital programme. No need to amend the current development bids meantime. JNF

3.1.1.2.7 Further efficiency savings (4.2 of paper) £199,000.

Noted: This is the full year effect of the additional efficiency savings offered. The proportion in the current year is still to be determined. The savings to be a contribution to a common pool. Dr McClelland said he could confirm his offer of £50,000 in principle but subject to the assurances he had sought via key questions he had posed about the rules of this particular game. These were discussed and the following agreed:-

Agreed:

a) Baseline budgets:

It was agreed that the baseline budgets from which the savings will be made must be agreed absolutely and that they should include estimates of the sums likely to be available later in the year to cover salary awards and inflation.

b) Deployment of Savings:

Directors will retain a significant influence over the deployment of savings offered for the common good, negotiating year-by-year which proportion should be available for recycling within the Centre and which offered to the pool.

ACTION

c) Unit Costs:

The need for clear accurate unit costs is agreed. Work has begun to update and to supplement the original Lapsley/Mitchell work and will be pursued vigorously. JNF

d) Written protocol for handling efficiency savings:

Mr McIntosh and Mr Francis to prepare a draft protocol for consideration. DMcI/ JNF

e) Starting date for developments:

It was agreed that developments in the 'first call' section of April paper (total £232,600) can be commenced. Directors and Mr Francis to determine these by end June and make recommendations to Mr McIntosh. Anyone wishing to initiate a development in this category immediately should contact Mr McIntosh who will authorise a start.

3.1.2 Anti-HCV Testing

Agreed: Routine donation testing to begin on 1st September 1991.

3.1.3 R&D/Product Development Group Forward Plan

Dr Prowse had circulated the following documents on behalf of the Product Development Group:-

- The future role of biotechnology in the SNBTS
- Forward planning of product development

3.1.3.1 Biotechnology

Agreed: After full discussion the paper was approved as presented except for the substitution of 'DNA technology' in place of 'PCR' in those sections relating to the introduction of HCV and HLA-D assays.

Notes:

a) Monoclonal Antibody Grouping Reagents:

There is a need to evolve arrangements by which the National Reagents Manager can obtain new cell lines and develop new products in liaison with the Centres.

Mr McIntosh, Dr Mitchell and Mr Bruce to resolve this matter together, co-opting members from RTCs as required. DMcI

ACTION

b) Basic Science:

It was agreed that proposals regarding basic science developments in biotechnology, including aspects relating to diagnostic reagents and methods (other than HLA-D and HCV), be brought to the October 1991 Board meeting. CVP/TDs

c) Therapeutic Products:

It was agreed to freeze developments of licensable therapeutic products at their current stage until suitable external collaborations are found. The PFC should continue relevant research into a cell culture medium which may include work on hepatitis B and rhesus (D) antibodies. CVP/RJP

3.1.3.2 Forward Planning of Product Development:

3.1.3.2.1 Group I

After discussion the following, in priority order, were agreed as definite group I products which require firm individual proposals for development and manufacture (items 1-6). Items 7-10 were agreed as "candidates for inclusion in Group I, but subject to further analyses".

1. HP FVIII: (Note: Once HP 8 is fully developed, it will still be possible to manufacture an intermediate product - probably S8 - if required).

2. HP FIX

3. Improved Albumins

4. Improved Immunoglobulins

Agreed: Detailed plans for HP VIII and HP IX have already been approved by the Board, while (3) and (4) are developments at minimal costs that are already in hand within PFC.

5. Fibrin Sealant: The demand for this product could become very high once clinical efficacy and viral safety are demonstrable. Due to the potential for cross-contamination with the thrombin component of this products it was agreed that it would not be manufactured within the current PFC production facility, but would be purchased as pre-vialled material.

6. Haemoglobin: The possibility was discussed of red cells being superseded by such a product within 10 years. With older or current products, problems of renal toxicity and respiratory reactions have been identified by other groups. Once these are overcome the product would well substitute for red cells in up to 40% of transfusion to surgical patients.

ACTION

Agreed: The above products (1 to 6) are the highest priority items and will be the subject of detailed business plans (for items 5 and 6, 1 to 4 having already been considered - see above - at least for the current proposed products) to be brought forward for Board approval in due course.

7. HP VWF

8. Anti-Thrombin III:

Agreed: Following discussion it was proposed that these two products be reconsidered as Group I, rather than Group II, products since the Board felt that demand for them may justify in-house development. The PDG to provide an option appraisal for these two products to the Board in due course.

9. Alpha-1-Protease Inhibitor: A controversial product but licensed by the FDA, uniquely, on the basis of a phase I trial, so a demand is expected.

10. Virally Cleared Plasma: Professor Cash explained that fresh frozen products which are not "virus free" may soon become unacceptable. Bedside filters are being developed which might filter out viruses however and if this development is successful there could be no need for plasma to be virus inactivated in bulk.

Agreed: accept the forward plan in principle, each proposal to be submitted separately to the Board. In addition a review of the development of each product to be given annually to the Board.

Agreed: when the business plan is proposed it must cover development staffing implications in full, in addition to other aspects.

3.1.3.2.2 Group II

It would be more appropriate to secure this group of products through central contract and issue to Health Boards. Dr Prowse's proposals for this group were accepted.

The Board congratulated Dr Prowse and Dr Stewart for the documents presented by Dr Prowse which contain highly valuable information unobtainable elsewhere. Dr Stewart to receive a MC copy of the minute.

ACTION

N.B. The highly confidential nature of the documents was noted. In future, each page to be marked 'confidential': circulation to be restricted to Board members and selected staff immediately involved in relevant work only. ALL

3.1.4 SNBTS Donor Services (9/10 April)

Mrs Thornton introduced her paper and answered questions. She tabled a draft comparing whole blood donor attendances in West of Scotland over 3 consecutive years including 1990-91. The highly favourable trend was noted with pleasure.

She also explained the work being done to identify and to "track" new donors who had volunteered during the Gulf Crisis. The results of this work should be ready later in the summer.

Agreed: Mrs Thornton to produce a routine report every 6 months. MT

3.1.5 Strategy for IT (deferred from 9/10 April)

Mr Francis had circulated a paper entitled 'Information Strategy Update'.

National IT Unit: It was noted that a development has been approved for two additional staff needed to ensure that the scheduled developments take place.

Computer Audit: Mr Francis explained that an external professional computer auditor would be selected by 31st July to undertake an initial audit of all existing systems.

Resource Management Systems: It was noted this phase was intended to refer to business support systems of all kinds, including for instance personnel systems and stores systems.

3.2.0 ITEMS FOR DISCUSSION

3.2.1 Donor Services Development Project

Mrs Moira Eadie and Miss Lyndsay Small introduced the above on the basis of papers which they had circulated and answered questions.

The Board congratulated them on the progress being made and Directors in other Centres looked forward to its extension.

3.2.2 Product Liability: Product Safety

Mr McIntosh had written on 28th May to Professor Cash whose interim reply dated 3rd June was tabled.

The following points were noted:-

3.2.2.1 Positive donor identification: The MSC are considering and will report to the Board. MSC

ACTION

3.2.2.2 ALT and/or anti-core testing: After a thorough discussion it was agreed the MSC should consider ALT and anti-core testing from the professional point of view and report to the Board. The final 'political' decision would almost certainly have to be a UK one, but could be influenced by the SNBTS view. MSC

3.2.2.3 First time donors red cell discard: Professor Cash confirmed he had asked Mr Moores to undertake an investigation into the likely effect of this on stock levels as a high priority in IT Research and Development.

Agreed: To continue this topic at a special Board meeting to be held as soon as possible, to cover this and other important items for discussion.

3.2.3 Red Cells

Dr Stewart is continuing to co-ordinate analysis of red cell requirement in preparation for the Supply and Demand meeting on 10/11 September 1991.

3.2.4 SNBTS Reorganisation: Our ways of working

To be discussed at a special meeting. MC

3.2.5 Total Quality Management in the SNBTS

(deferred from 9/10 April) To be discussed at special meeting.

3.2.6 HP FVIII

Noted: On target.

3.2.7 Plasma Targets

To note that the Edinburgh total of fresh plasma to PFC is 17,275kg giving a revised total for Scotland of 71,275kg.

3.2.8 PES - 1991 and preparation for 1992

MC

To be discussed at the special meeting.

3.2.9 MSC/Bone Marrow Transplantation

The MSC had met on 15/16th May and a briefing note had been circulated with agenda.

Concerning the unrelated BMT donor panel it was noted that Dr Urbaniak had agreed to take over from Dr Crawford as the Scottish Consultant leading the programme. It was agreed that he should replace Dr Crawford and Dr Yap on the NBTS Group on Unrelated BMT. SJU

The unsatisfactory arrangements in England and Wales and the predominance of the Anthony Nolan panel were noted.

ACTION

Mr McIntosh agreed to explain to Chief Executive of the NHS in Scotland if necessary that the SNBTS might not be able to collaborate with England and Wales. Professor Cash to speak first to Dr Ian Fraser at the NBTS annual scientific meeting for consultants which they would both attend on 13/14th June and report back.

Professor Cash to write to Dr Crawford and Dr Yap. JDC

3.2.10 Red Cells sent to Germany

It was noted that Dr McClelland had received an urgent request from Munster for 150 units. He had researched so far as he could the status of the requesting body (a broking agency) and had managed to confirm with the hospitals themselves that they do in fact receive cells from this agency. The latter had signed the required declarations that the cells were for use on a non-profit basis only and that no product liability lies with the SNBTS.
Agreed:

a) Dr McClelland to charge the private sector handling charge. EMcC

b) Such emergency requests to continue to be treated on an ad hoc basis using the procedures established, clearing each case with Mr McIntosh or Professor Cash on each occasion.

c) SNBTS future policy with respect to any possible long term export arrangements to be the subject of further Board discussion.

3.3.0 ITEMS TO NOTE

3.3.1 Year-end Performance Summary

Mr Francis had prepared a paper which had been circulated.

Performances had been highly creditable in all areas.

3.3.2 Relationships with Private Hospitals 1991-92

Noted: The only report now awaited is that in respect of Murrayfield, Edinburgh.

3.3.3 Unit Costs

A paper headed 'Product and Service Costing System' prepared by Mr Francis had been circulated with the agenda. An external consultant had been commissioned to undertake a study towards an effective costing system. Meanwhile the NBTS system, which had its deficiencies, would be used on a trial basis.

3.3.8 HIV Antibody Positive Donors

Cumulative figures to 31st May 1991 were tabled.

4.0 DATE OF THE NEXT MEETING

A special 2-day meeting to be arranged in July or August for the items noted above. Thereafter, 10th September (Supply and Demand) and 11th September.