PRC

1986

STC(M)81/1
STC (M) 80/5

IN CONFIDENCE

THE NATIONAL BLOOD TRANSFUSION SERVICE

SCIENTIFIC AND TECHNICAL COMMITTEE FOR THE CENTRAL BLOOD LABORATORIES

MINUTES OF THE 8TH MEETING OF THE COMMITTEE HELD ON WEDNESDAY 3 DECEMBER 1980
AT THE DEPARTMENT OF HEALTH AND SOCIAL SECURITY, HANNIBAL HOUSE, ELEPHANT AND CASTLE

PRESENT: Professor P L Mollison - Chairman
Dr P Dunnill
Mr R D Smart
Dr J Prydie
Dr B A Wills
Dr G H Tovey
Dr H H Gunson

DIRECTORS

Dr A M Holburn
Dr R S Lane

JOINT SECRETARIES

Mr S Godfrey
Dr D Walford

IN ATTENDANCE
Mr Ayling - Medicines Insp.
Mr J Harley
Mrs S C Yuille

APOLOGIES FOR ABSENCE

1. Apologies had been received from Professor Flute and Dr Gunson.

MINUTES OF THE PREVIOUS MEETING - STC (M) 80/4

2. These were agreed.

MATTERS ARISING

a. Technology Working Party - STC 80/6

3. Dr Dunnill speaking to his paper, STC 80/6, explained that the Working Party had most recently met in July and September and the report was the result of their deliberations. It had not yet been possible to prepare the appendices which were referred to in the report. The key points of the report were contained in paragraphs 2.1 and 3.6.

4. Paragraph 2.1 pointed out that a considerable number of technical problems needed to be resolved before building of the new plant could begin. A full-time plant engineer to co-ordinate planning, followed by a specialist architect and a consultant engineer would be needed. Only with their expert advice could the costs of a new facility, which would conform to Medicine Division's requirements, be gauged. It was considered that building should be completed in 1985 but no later than 1986/87. Dr Lane said that the question of a senior engineer was being discussed by the Department and the North West Thames Regional Health Authority but he had not heard what the outcome was. Mr Harley agreed to take the matter up with the Department's Personnel Division.

5. Paragraph 3.6 outlined the need for good pharmaceutical practice and safety measures. It was considered vital to seek the Medicine Inspectors' views and guidance throughout the planning and building stages. A form of critical path analysis would be needed.

6. It was important to know how the PFC Liberton would cope with its trial shift system and members supported the proposed experiment. Dr Walford explained that Dr Cash, the National Medical Director of the Scottish Blood Transfusion Service, was of the view that by the end of the decade the United Kingdom would need one million litres of fresh frozen plasma to meet demand for blood products. Dr Lane thought that an increasing trend towards home therapy of haemophiliacs would push up the requirement for factor VIII. In some countries the level of usage per patient was 50-55,000 international units of factor VIII per annum; this would equate to 1,000 tonnes of plasma per annum.

7. **The Working Party felt that it was extremely important to continue to expand research into improving the yield of Factor VIII.**

8. Dr Tovey said that representatives of Transfusion Directors together with Dr Cash and Dr Lane would be meeting in January to discuss the likely quantity of plasma which the UK could collect. On the basis of these discussions the group would then meet Haemophilia Directors to talk about requirements for factor VIII and how far these could be met. Dr Tovey would report the outcome of these meetings to the Committee in due course.

9. Dr Dunnill considered that one way to meet factor VIII demand in future might be by genetic engineering which had already been used successfully in the production of insulin and might be employed in the manufacture of blood products.

b. BPL RIA Test

The parts covered do not relate to the matters in question in this Action.

b. BPL RIA Test

10. Dr Walford explained that since the Committee's last meeting the Department had agreed that from 1 March 1981 - or earlier depending on whether the Burroughs-Wellcome test and equipment were ready - BPL should be allowed to market its test to RTCs at a cost of 20 pence per test. The cost per test had been made as comprehensive and competitive as possible and took account of greenfield development costs and included a profit margin. Burroughs-Wellcome had now been informed of the Department's decision to market the BPL test next year. Mr Smart suggested that the price should also have contained an element to reflect the costs of the central administration of the BPL analogous to commercial "head office costs". Dr Lane's request for funds to start production of the test was being considered by the Department.

THE BLOOD GROUP REFERENCE LABORATORY'S SCIENTIFIC PROGRAMME - STC 80/8

11. Dr Holburn tabled a list of his scientific staff; because of insufficient space at Chelsea some of these were working elsewhere.

12. Speaking about the production of ABO grouping reagents Dr Holburn explained that the laboratory's production had not greatly increased since 1971 and there had been a fall in output and potency of products in 1979/80. This was mainly because of a reduction in the supply by Regional Transfusion centres of 'high titre' plasma from naturally immunised donors; the best plasma was being retained by the Centres. Meanwhile, the cost of commercial equivalents had risen sharply in recent years, and it was likely that £1½ million worth of ABO reagents alone were currently being purchased commercially.

13. Dr Holburn felt that a considerable improvement in potency and quantity could be achieved by using plasma from hyper-immunised donors. A few Centres, for example Lancaster and Brentwood, were recruiting donors for hyper-immunisation, but it was thought that many Directors were worried about the process of hyper-immunisation because they felt that there was no officially agreed form of compensation for donors in the event, albeit unlikely, that they suffered a mishap as a result of hyper-immunisation. Dr Tovey said that anxiety over compensation had also been expressed at a recent EEC meeting.

14. The Chairman wondered whether there was in fact a compensation problem and

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REDEVELOPMENT OF THE BLOOD PRODUCTS LABORATORY

23. Speaking about progress with the short-term upgrading programme Dr Lane said the installation of the modular cold store had now been completed and it was already functioning. The Regional Health Authority had now taken over the management of building projects and it was anticipated that work would be finished by the autumn of 1982. It was inevitable that certain areas of production would be disrupted by the redevelopment programme and it was therefore vital to accelerate building in these sensitive areas. Dr Lane said that he would prepare a paper for the Scientific and Technical Committee, the Joint Management Committee and the RHA on the areas of production which were most likely to be affected.

24. As for the long term redevelopment, staff at BPL had been relieved at the announcement of Ministers' decision not to involve industry in management of the laboratory.

encourage its wider use. Already the number of hospitals using the new product had risen to 25, about 6% of all hospitals.

19. BGRL also wanted to be able to provide an independent quality control service to RTCs, which were producing anti-globulin reagents of variable quality.

20. Dr Holburn thought that eventually the production of all reagents would have to be centralised at the BGRL, and especially when suitable monoclonal anti-bodies became available. The Chairman agreed that the distribution of standardised reagents from a single centre was desirable and considered that the Laboratory should charge for its products in the same way that BPL intended to charge for its RIA test. The Health Service should be encouraged to buy BGRL's products in preference to commercial and other products. Mr Smart thought that if BGRL were to compete fairly with commerce its products would have to be appropriately dressed, packaged and distributed. This was accepted.

21. Members agreed with Dr Tovey's suggestion that he should copy the report to Regional Transfusion Directors to assist them in discussing ways of rationalising the production of reagents in the Blood Transfusion Service, and improving the supply of raw materials to BGRL.

22. Dr Holburn agreed to produce a paper for the Scientific and Technical Committee and the Joint Management Committee detailing the long-term objectives of BGRL.

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25. Mr Harley said that the Department had already started to draw up plans for the long-term redevelopment of the Laboratory. Dr Lane thought that in its present condition the Laboratory would probably only be able to function until 1984/5.

STAFF APPOINTMENTS IN QUALITY CONTROL AT BPL - STC 80/7

26. Dr Lane said that one of the Medicines Inspectors' recommendations had been that there should be a quality control programme at BPL. Dr Lane had accordingly prepared proposals for a programme which would monitor the safety of BPL products. His proposals included the appointment of a senior person as head of quality control. (HQC). Dr Lane had originally envisaged that the post would be filled from within BPL but he now accepted that this would have to be an external appointment.

27. Discussing Dr Lane's proposed staffing structure Dr Prydie was concerned that the HQC appeared to have no direct control over the analytical laboratories. Dr Wills agreed that that there should be such control and thought that the HQC had to be free to decide on the priority of work undertaken without constant need to refer to the Director. Equally, Dr Prydie thought that the heads of the analytical laboratories should report direct to the HQC. Dr Lane said that he envisaged that there would be feedback to HQC, especially on assay control and HQC would be able to exercise control through documentation. Mr Smart said that the lines of control and functions of staff needed to be clearly spelt out.

28. Asked how his proposals would be affected by expansion Dr Lane said that this would be studied in a work control analysis.

29. The 4 other staff which Dr Lane envisaged as part of the quality control team would be responsible for documentation, data control, liaison with RTCs. There would also need to be secretarial and clerical assistance.

30. Dr Prydie saw the need for a quality assurance auditor. Dr Lane said that he thought that one of the 4 staff could take over this function.

31. It was agreed that having received the advice of the STC Dr Lane should re-examine the quality control programme structure and the HQC job description in consultation with Dr Wills, and a revised paper would then be sent to Mr Harley before being put to the STC and the JMC.

MEETING OF THE ADVISORY COMMITTEE ON THE NBTS

32. Mr Harley said that the Advisory Committee had met for the first time on 1 December, and had reviewed some of the problems with which it would be faced at its future meetings. Dr Tovey explained one of the major topics on which members had received papers was the increase of plasma for the BPL.

ANY OTHER BUSINESS

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33. Mr Harley thought that there were additional areas of research which might be undertaken at the Central Blood Laboratories and he asked members for their suggestions. The Office of the Chief Scientist would be asked to sponsor any such work. Dr Dunnill said that before a new facility could be built at Elstree various technical problems needed to be researched and this would be a good opportunity to do so.

34. Members agreed to forward brief details of their suggestions to the Secretary. Proposals could then be discussed at the next meeting.

Medicines Inspection at PFL

35. Dr Lane wondered when Medicines Division would be inspecting the Protein Fractionation Laboratory as their report would assist him in coming to a view on the future of the Laboratory, and whether its work could be absorbed by BPL. The Secretariat agreed to check this with the Medicines Inspectorate.

DATE OF NEXT MEETING

36. This will take place on 4 March 1981 at 2.15 pm.

December 1980 DHSS