NOT FOR PUBLICATION

NATIONAL BLOOD TRANSFUSION SERVICE -
SCIENTIFIC AND TECHNICAL COMMITTEE
FOR THE CENTRAL LABORATORIES

Meeting at the Blood Products Laboratory, Elstree on 26 March 1979

Present: Professor P L Mollison (Chairman)
Dr P Dunnill
Professor P T Flute
Dr H H Gunson
Professor D K Peters
Dr J Prydie
Mr R D Smart
Dr G H Tovey
Dr B A Wills
DIRECTORS
Dr A M Holburn
Dr R S Lane
JOINT SECRETARIES
Mr T E Dutton
Dr Sheila L Waiter
IN ATTENDANCE
Mrs S C Yuille

1. Consideration of the proposed Terms of Reference - STC 79(1)

The Chairman welcomed members and invited their views on the Terms of Reference which had purposely been drafted in somewhat wide terms. Mr Smart thought that they were too introspective. He suggested that, in view of the dependence of the Central Laboratories on the supply of plasma etc from Regional Transfusion Centres, there should be a reference to external relationships. The Joint Secretaries were asked to prepare revised Terms of Reference for consideration at the next meeting.

2. Discussion with the Directors on the functions of their laboratories - STC 79(2)

a) Blood Products Laboratory

Members had before them a memorandum, STC (79/2). The Chairman introduced the Directors and expressed the hope that members who had toured the Blood Products Laboratory had found the experience valuable. He drew attention to the confidential nature of much of what they had seen and of the proceedings of the Committee generally. There would be an opportunity, later, to visit the Plasma Fractionation Laboratory (PFL) at Oxford, and the Blood Group Reference Laboratory at Chelsea. The PFL was situated in the grounds of the Churchill Hospital at Oxford and the BGRL was located in Lister Institute premises at Chelsea. The Department held a long lease from the

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Institute on the main BGRL building, but some of the laboratory space was rented on only a month by month basis. It was hoped to move the BGRL to Oxford as soon as this could be arranged and the Oxford Area Health Authority (Teaching) had been asked to reserve most of the Harkness Building, situated in the grounds of the Old Radcliffe Infirmary, for this purpose.

Dr Lane outlined the constraints on the development of BPL due to its situation on a restricted site within the grounds of the Lister Institute. The Department had now made an offer to purchase the whole of the Lister Elstree site so that over 30 acres would be available for future development. The importance of factor VIII and albumin in dictating the ultimate size of the production capacity needed at BPL was discussed. Usage of factor VIII in the United Kingdom was probably about 60 million international units. Current NHS production was equivalent to about 30 million international units but only about 13 million international units were being produced as a concentrate by BPL , the remaining 17 million being issued as cryoprecipitates by Regional Transfusion Centres. The present commercial price of factor VIII was about 10p a unit so that about £3 million was already being spent annually on commercial factor VIII concentrates. If the current rate of increase in usage continued, and if BPL production were not expanded, the cost of factor VIII concentrate to the NHS might reach between £14 million and £24 million by 1982.

Mr Smart pointed out that with expenditure of this order likely to be incurred, there appeared to be every incentive on economic grounds for speedy investment aimed at optimising factor VIII production at BPL.

Dr Tovey said that if the publicity was right there would be no difficulty in obtaining all the plasma necessary to support a factor VIII production programme rising to 100 million i.u. per annum, which was seen as the eventual requirement by some clinicians. Professor Peters suggested that the Committee might examine these estimates of future requirement more closely and after discussion it was agreed that if clinicians were to retain freedom to treat their patients in the way that was considered most suitable, it was possible that eventual requirements might well approach the 100 million i.u. per annum mark. Dr Tovey referred to the embarassment which he would experience if it became generally known in the South West that large amounts of commercial factor VIII were being purchased. For two years there had been more donors than the NBTS could handle. He pointed out that any further expansion of BPL plasma processing capacity would have to be matched by expenditure in the Regions producing the plasma.

The possibility of a plasma production programme specifically dedicated to the production of fresh frozen plasma of the highest quality in order to provide the optimum starting material for BPL production was discussed. The need to involve Regional Transfusion Directors at all stages and preferably give them the control of issues of factor VIII in all forms was emphasised, since only then could they properly plan plasma production.

Dr Lane pointed out that factor VIII production was the cornerstone of NHS blood products production and the requirement for this factor would control the amount of plasma which had to be collected. The finished product should form the basis of NHS supply of factor VIII (topped up as necessary by commercial factor VIII until complete NHS self-sufficiency was achieved) and its distribution should be in the hands of the NBTS.

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Dr Dunnill reminded members that he had pointed out to the Department some 12 months ago that it was improvident to expect the major BPL plant to continue to function much longer without major breakdown. Mr Smart also commented on the lack of spare production capacity and recommended that the Department should provide for the largest production it was likely to need and to plan to have the plant run at 60% of this capacity, thereby providing adequate spare capacity to allow overhauls, breakdowns etc to be dealt with without interruption of normal running. The importance of planning so as to provide the maximum flexibility in use was emphasised. Dr Dunnill also stressed the need to concentrate on improving yields since any substantial improvement could go a long way towards meeting the present short-fall of factor VIII.

Dr Lane pointed out that the 'stop-gap' programme, which was designed to give maximum production capacity essentially within the constraints imposed by existing plant and premises, was not capable of being repeated, and there was an urgent need for the planning of substantial additional capacity.

The Chairman invited members to consider how a start might be made in designing new plant. Dr Dunnill advised the Committee to think in terms of a new operating system, rather than simply in terms of the plant required. After discussion it was agreed that a thorough study of methods, through-puts, yields and quality at as many fractionation plants as possible was an urgent necessity. Thereafter it would be advisable to separate the planning engineering requirement from the subsequent processing engineering requirement. Mr Smart thought that if the plant was properly designed and run the 'payback' period would be very short.

Dr Lane said that from what he had heard about engineers' salaries at the level of expertise needed it was unlikely that suitable people could be recruited. He doubted whether the laboratory could ever be satisfactorily staffed with scientists and technologists if the Department were to insist on applying NHS terms to them. The BPL was dependent for its functioning on staff whose normal outlet was not the NHS, but manufacturing industry.

Mr Smart invited the Committee to consider recommending to the Department that they appoint a retired senior engineer from the pharmaceutical industry to plan the kind of laboratory which would be needed. He was sure that there were some very competent engineers who would be willing to carry through the planning stages for a relatively small consultancy fee. It would not be immediately necessary to appoint a process engineer. Dr Lane pointed out that if the planning and building of a totally new operating system was likely to take long it might be necessary to consider the phased redevelopment of much of the existing plant. Mr Smart thought that if this should prove to be necessary it should not hold up the total replanning of BPL.

Professor Peters felt that further consideration should be given to eventual requirements for other blood products (principally protein solutions) before any major planning was embarked upon.

Dr Gunson invited the Committee to consider whether there was a case for separating the two distinct functions in which BPL was engaged. There was a need to develop, and if possible exploit, the alternative methods to Cohn fractionation on which BPL was currently working, and the laboratory had various other research and development projects in hand. At the other end of the scale was a routine production process turning out large quantities of plasma proteins by established methods. He wondered whether there was a place for industrial participation in the latter process.

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Mr Smart said that he saw no purpose in handing over the routine fractionation to industry. The BPL had shown that they could do the job, given the resources, and if they could achieve the same efficiency as industry, which he had no reason to doubt, the BPL could save the NHS large sums of money which could be used to relieve pressures elsewhere. If the Committee were agreeable, Mr Smart was prepared to discuss the requirements further with Dr Lane and prepare a comprehensive report which members could consider at their next meeting. The report would have regard to the earlier plans, so far as they were still felt to be appropriate, which Dr Lane had prepared. Members agreed to this suggestion since the report appeared to offer a firm basis from which the Committee might make a recommendation to the Department.

b) Blood Group Reference Laboratory

Dr Holburn described the functions of the Blood Group Reference Laboratory, which not only prepared large volumes of serological reagents which the NHS would otherwise have to buy, but also had a number of important reference functions. He also outlined his plans for developing the laboratory's functions, but drew attention to the constraints on any extension of activities unless the laboratory was rehoused in more suitable premises.

3. The Committee's future programmes, including frequency and venue of meetings

It was agreed that the next meeting should be at the plasma fractionation laboratory at Oxford, the third meeting possibly being held at BGRL, by which time it might be possible to consider BGRL's functions in relation to a more suitable laboratory, where functions could be expanded. Dr Holburn undertook to prepare an expanded account of BGRL's functions for this occasion.

It was agreed that meetings should take place four times a year, the next meeting being held on whichever of the dates – 1st, 4th, 7th June – was most suitable to (PFL) the hosts. The following programme was suggested : 11 am – visit Oxford Regional Transfusion Centre primarily to see plasma production facilities: 12.00 – look round the Plasma Fractionation Laboratory: 1.15 – lunch: 2 pm – meeting of the Committee:

(The Regional Transfusion Centre and the Plasma Fractionation Centre are almost adjacent in the grounds of the Churchill Hospital, Headington, Oxford)

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