TRENT BLOOD TRANSFUSION SERVICE

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Dear John

With regard to the list of topics left by Bain for resolution at NBA level, I believe it will help me to clarify my own thoughts by putting them on paper in advance of discussion at the Executive meeting.

1. Plasmapheresis

The policy for the next three years is virtually fixed by a combination of BPL requirements and the fixing of a unified price for plasma, irrespective of its method of procurement. All centres will now inevitably, over this time span, reduce their "ordinary" plasmapheresis activity to as near zero level as possible. However, plasmapheresis will still probably be used for the harvesting of immune plasma, and I know that there is a body of feeling within the four "major apheresis centres" that the majority of this supply should come from those four centres. In addition, and after discussion with our Regional clinicians, we intend to switch the provision of clinical fresh frozen plasma to apheresis, thereby releasing more recovered plasma for fractionation at BPL. This has the added advantage of being a preferred clinical product in that it reduces donor exposure so far as patients are concerned. By a combination of these two continuing plasmapheresis activities, and the probable need to harvest platelets by apheresis, I believe that we can and should maintain our expertise in the field against the time when circumstances change and increased demands for plasma are made on us.

2. Platelets

Given the fact that single donor platelets obtained by apheresis are increasingly being accepted as a superior clinical product, I believe that the move to apheresed platelets will continue. There must be continuing local financial monitoring however of the costs of this procedure as compared with the financial benefits of producing recovered platelets, from the same donation coming a unit of SAGM cells and some plasma for fractionation. I

TRENT BLOOD TRANSFUSION SERVICE

To: Mr J Adey

Continuation: 2

Date: 7 December 1993

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believe that this particular financial equation will vary from centre to centre, given the comparative ease or difficulty of returning donations to base for component preparation. Additionally, however, apheresis is our only means of coping with the ever increasing demand for HLA typed platelets. There is no doubt that of the current machines, the COBE Spectra is best equipped for producing apheresed platelets, but there is a good deal of attraction in the emerging Haemonetics technology which would enable us to switch the use of the machine between any combination of three components, platelets, red cells and plasma. The COBE machine is superb for platelets, but hopeless for plasma. So far as recovered platelets are concerned, it seems inevitable that over the next one to two years, most centres will pursue the top and bottom bag system in some form or other, as the means of producing a clinically superior recovered platelet concentrate. The slightly increased cost of such platelets should be offset by the reduced need in the hospitals for leucocyte filtration before transfusion.

3. Bag Cost Reduction

The working party already set up seems to be tackling the problem reasonably well, and we now have the prospect of not only breaking the IPP monopoly (given the success of BPL tests of an alternative opening device) but also of being involved in a national contracting process which will have a sufficiently high NBA professional input to give all of us maximum benefit.

4. ALT Testing

As things stand, I can envisage this only being adopted for the facilitating of "selling" plasma outside the UK. Should this be the case, a difficult decision must be made if recovered plasma is to be considered for inclusion in outside sales. If we test whole blood donations for this purpose, then we must face the fact that cellular components may be obtained from an individual whose ALT cut off level is above that which is acceptable for source plasma for fractionation. What do we do with the cellular components?! The concept of having a two-tiered testing system on whole blood donors, depending whether or not their plasma is to go outside the UK, is probably unworkable. We would in effect be introducing full scale ALT testing by the back door under these circumstances, and this again is probably unacceptable. This leaves the alternative of producing plasma for outside consumption by apheresis only, as was mooted by BPL some three and a half years ago when they were exploring a European market for one of their products. Testing of apheresis donors is workable, since no cellular components for transfusion are involved. It worked perfectly well last time, except that BPL withdrew from the field, and abolished the premium for ALT testing which had been agreed with the centres involved. This left those centres, including Trent, with a fairly expensive machine leased for this purpose, now being used only for occasional quality assurance work. As you can imagine, we do not want to be left in a similar situation again! Incidentally, I believe that the machines obtained at that time were all of a similar type, the Epos

continued .....

TRENT BLOOD TRANSFUSION SERVICE

To: Mr J Adey

Continuation: 3

Date: 7 December 1993

machines, the workings of which would not be acceptable under current more stringent quality requirements. On the basic level, there is no method of sample identification built into this system, and I feel that we cannot operate under these circumstances for widespread screening of plasmapheresis donors. The capital cost of new machines to enable us to cope with ALT testing would therefore have to be taken into account.

5. Diagnostics

In common with at least the bigger centres, we have a reagent production department which has (in our case) recently been subjected to in-depth financial scrutiny. The report suggests that the department is cost effective, producing as it does reagents for in house use, for use in hospitals in Trent Region, and basic materials for BPL Diagnostics. However, we are very conscious of the fact that after 1996 we will probably need a licence from the Devices Directorate to enable us to continue these activities. Perhaps the time has come for all RTC reagent producers to be specifically audited against the "Red Book" Guidelines to assess the likelihood of compliance with Devices Directorate requirements, which are at the moment unknown. It seems likely, though, that the Directorate will take the relevant chapters of the "Red Book" as their starting point, as the MCA do. I suspect that BPL(D) is in exactly the same position, with the added complication of needing to be financially viable in the open market. There is no doubt, however, that there is a good deal of expertise within the NBTS with regard to the production of polyclonal and monoclonal raw materials, so perhaps we should be urgently exploring the possibility of a commercial tie up with a company who would take these raw materials for the production of final diagnostics measuring up to Devices Directorate and FDA standards.

6. Marketing Plan

I feel that an RTCs marketing plan in the middle and long term will be based firmly on a common costing system. This will be a pre-requisite for the identification of apparent anomalies in pricing structures, and should enable correction where necessary and possible. Hopefully this will therefore reverse any wild differences in prices to customers across the country, and lessen enthusiasm for change on the part of these purchasers. Given the ethos of the Health Service reforms however and the aggressive attitudes taken by Chief Executives of Trusts, I personally doubt whether the fixing of a national price for cellular components will be acceptable, attractive though it may be to those of us who currently have components priced below the mean! Enthusiasm for take over bids at RTC level may also be tempered when the application of a common costing system allows true comparison of apples with apples, but this will still need efficient monitoring from NBA headquarters to combat aggressive selling tactics which would be detrimental to donor attitudes.

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TRENT BLOOD TRANSFUSION SERVICE

To: Mr J Adey

Continuation: 4

Date: 7 December 1993

Within a Region's marketing area, it is essential to ensure proper professional contact,across all disciplines, so that each side is aware of developments and demands. Once a Region's range of products and prices have been established, I feel it best that marketing and contracting be left at this level, though it is essential that we reinforce feedback on customer satisfaction, not only for managerial attention at RTC level, but for central collation at NBA headquarters.

7. Research Plan

One of the more delicate areas. I feel it will be essential to establish an NBA research committee, with a mainly medico-scientific input but with sufficient representation of other disciplines to allow consideration of projects involving, for example, business management or donor management. A trawl of ongoing R&D activity at RTC level has already been performed, I feel that the research committee would need this to be updated, together with details of funding and completion dates. All new suggested projects, of course, would be submitted to the committee for assessment, and to ensure that there is no duplication of effort and spending between centres.

Funding of research is perhaps going to be the most problematic area. At a national level, it seems unlikely that the Department of Health will allocate a specific research sum to the NBA, though I am sure that no harm would come of contacting Professor Michael Peckham who heads the NHSME Research and Development Directorate. Incidentally, this Directorate has set up a Standing Group on Health Technology (SGHT) chaired by Professor Miles Irving, which advises the NHS Central Research and Development Committee. SGHT is itself advised by six panels, two of which are the Diagnostics and Imaging Panel and the Acute Sector Panel, which would between them cover most research activities envisaged within the field of transfusion medicine. Various authorities and organizations have been consulted by SGHT, which sought their advice on topics which might be considered for national funding. Given the timing of this consultation, I doubt very much whether the NBA was included in their consultation list, but it might be worthwhile pursuing this particular avenue of funding.

Still at a national level, I doubt very much whether the MRC would agree to allocate funds en bloc to the NBA to be administered by its research committee, and I also feel it extremely unlikely that purchasers would accept the imposition de novo of a research levy on all components etc supplied.

At RTC level, there are still one or two avenues either open or worth exploring for research funds.

i) As now, RTCs would actively seek out external funding for projects, or fund them from identifiable non-recurrent savings within the budgets. From a political and sensitivity point of view, it would probably be better if any approach to a commercial company for a research grant be made locally rather than by the NBA research committee.

TRENT BLOOD TRANSFUSION SERVICE

To: Mr J Adey

Continuation: 5

Date: 7 December 1993

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ii) At the present moment, Regionally organized research funds exist at RHA level, against which RTCs may bid for specific funding of a project. With the demise of RHAs, these funds will presumably be devolved to more peripheral organizations or individuals with responsibility for research. Perhaps an RTC's "share" of these RHA monies could form part of the negotiation between RHA and NBA for the handover.

iii) Currently, RTCs are able to bid for funding against local university funds. This of course could continue, but it must be remembered that the chance of success at the moment is much enhanced by all senior medical staff having honorary status with the university in their contracts of employment. It might be wise for Anne Mather to establish the principle that this honorary status will not disappear with the transfer of contracts from RHA to NBA.

iv) When a properly broken down table of current research activities at RTCs is available, with details of funding source and expected time of completion, it might be possible to begin a sympathetic programme of top slicing from centre budgets funds which have been specifically allocated as recurrent research funds from the RHA.

8. RTC Performance Standards

Professionally, standards are established by EC Directives on GMP, mirrored in the UKBTS/NIBSC Guidelines ("Red Book"), and by the Clinical Pathology Accreditation organization. The NBA as a whole is very much involved in the setting and monitoring of the standards adhered to within the UK, and it is essential that these standards remain the benchmark since they represent levels of acceptability to be applied to all of the UK. The newer parts of the NBA will obviously need to have an input into the existing machinery, but it is essential that we do not allow the wheel to be re-invented. Monitoring of performance against these professional standards is carried out by the MCA for licensing and by CPA for clinical laboratory accreditation, the system of audit established by the National Directorate of the NBTS is now, quite properly, being further developed by the Medical Director and Quality Assurance Manager of NBA. This system promises to work well.

So far as management performance standards are concerned, these will to a great extent be judged on a Regional basis by performance against targets based on contracted activity. The revamping of the Executive Information System should enable us to have a shot at producing acceptable national standards of performance against targets, ongoing monitoring of performance would then be routine by way of Regional returns to the EIS co-ordinator at headquarters. Since the EIS is being revamped by a series of working parties, it is to be hoped that they might have time to address the question of setting acceptable standards of performance for each topic within the system. However, if returns

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suggest that there are considerable differences in the way RTCs tackle a particular problem, it may well be worthwhile setting up a time limited working party to address individual topics, with a view to establishing a baseline of performance where patently no such standard exists. As with everything else, the imposition of a standard without investigation of widespread variation is counter-productive to say the least.

9. RTC Standard Costing System

I have referred to this already as the backbone of many of the future activities of the NBA. I know that this is on the go, with Barry Savery and Sharon van Turnhout already having met at least once with RTC representatives. Presumably they will be building on what has already been done at the working party set up by the National Directorate. In this working party more than most, it is essential that data from the whole country be available for study - the original (and now corrected) figures produced by Bain for plasma costings show just how misleading it can be to take a narrow snapshot.

I hope these ramblings have been of interest to you, it has certainly helped me to think out loud and get some of the thoughts down on to paper.

With kind regards

Yours sincerely

GRO-C

Dr W Wagstaff
DIRECTOR