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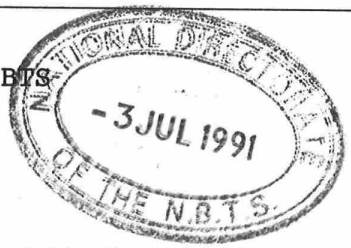


Your reference

Our reference

Date 29 June 1991

Dear Dr Gunson

**"BRAINSTORMING MEETING" ON THE FUTURE ARRANGEMENTS FOR BLOOD AND BLOOD PRODUCTS**

Further to Mr Malone-Lee's letter of 5 June on the above, I am writing to confirm arrangements which have been made for the meeting:

on: Monday 8 July 1991

in: The Lower Conference Room
Royal Society of Medicine
1, Wimpole St
LONDON
W1M 8AE

at: 10.45am for coffee starting promptly at 11.00am

A working lunch will be served at 1.00pm and tea at 2.45pm.

I enclose a background note and discussion papers. If you have any queries about these arrangements please do not hesitate to contact me.

Yours sincerely

GRO-C

MISS E M WEBB

POLICY - IN - CONFIDENCE

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**FUTURE ARRANGEMENTS FOR BLOOD AND BLOOD PRODUCTS : DISCUSSION PAPER FOR MEETING ON 8 JULY 1991**

Objectives and Constraints

1. This paper attempts to set out for discussion the DH view on the future options for the system comprising the collection of blood, distribution of cellular components, and fractionation of plasma into blood products, taken as a whole. The objectives for this system can be put as follows:

i) to encourage the voluntary donation of blood sufficient to meet the needs of patients in England (and Wales) for a safe and secure supply of blood and (subject to the exercise of clinical freedom) blood products;

ii) to ensure the safety of blood donors;

iii) to create incentives for the cost-effective use by clinicians of blood and blood products;

iv) to create incentives for the efficient collection, handling and distribution of blood and blood components;

v) to create incentives for the efficient fractionation of plasma and processing into blood products; and especially

vi) to ensure that plasma obtained as a by-product from blood donations is processed into blood products for use within the NHS, recognising that the marginal cost of doing so is smaller than the cost to the NHS of commercial alternatives.

2. The problem is that these objectives to some extent conflict. Thus objectives (iii)-(v) imply the need to create a competitive market and build in price signals for blood components and blood products; yet objectives (i) and (ii) are thought to inhibit the free operation of

such a/

such a market. This tension between the objectives underlies the institutional frustrations described in the Touche Ross report, in particular BPL's view that they are being expected to compete in a difficult market with unreasonable restrictions imposed on them by DH. Also objective (vi) cannot be achieved if individual players under present arrangements (RTCs, BPL) simply seek to optimise their individual objectives without considering the system as a whole.

**The Concept of CBLA as "Market Regulator"**

3. The strains in the present relations between DH, CBLA and BPL have lead CBLA to the concept of "uncoupling" their role from that of BPL. On this concept, RTCs would as now be required to collect blood as efficiently as is compatible with the safety of donors (and recipients). BPL would concentrate on the efficiency of the fractionation of plasma and on making better economic use of the existing plant. The newly-constituted CBLA would be responsible for creating and regulating the market in which the actions of each of the other individual players could be reconciled with objectives (i), (ii) and (vi). As a further development, it is suggested both by CBLA and by NBTS Directorate that the new CBLA should be combined with the NBTS Directorate to form a "National Blood Authority" with responsibility both for blood and blood products.

**The Plasma Input Price**

4. One key parameter is the price paid by BPL to RTCs for plasma derived from whole blood donations. Assuming that RTCs are required to cover the whole cost of blood collection by on-charging, the plasma price determines in turn the overall price level for the cellular blood components. There is no self-evidently "fair" way of determining what proportion of the collection costs should be loaded onto each component. In the absence of any effective market for cellular components, the best approach would seen to be to set the plasma price by reference to the price of blood products produced by BPL's commercial competitors. If the plasma price is set too high, BPL will lose market share, if it is set too low, BPL will have no incentive to efficient operation and we

will be/

will be vulnerable to the accusation that we are subsidising BPL and distorting the market. In between there should be a range of prices which would satisfy objective 1(vi) without too far weakening objective 1(v). It must be admitted that determining this range is not a straightforward exercise.

5. In contrast, we suggest that the price of plasmapheresed plasma should be freely negotiated with individual RTCs at a level which enables them to recover the capital cost of the equipment and operating costs. If no such level exists, further expansion of the plasmapheresis programme should be discouraged. There seems no sufficient policy reason for DH or the NHS to subsidise the costs of plasmapheresis.

## Variant Models for the CBLA Role

6. Within the basic concept of "uncoupling" there are a number of variations and these are described in the following paragraphs. We have not attempted to evaluate the options in the paper as we see this as one of the main purposes of the discussion on 8 July.

7. On **Model A**, individual RTCs would contract with BPL for fractionation of their plasma, and would market the resulting blood products to users in their own region (or possibly at the margin in other regions). CBLA's only role would be to act as the market regulator. Once the system had been set up, this would be likely to involve CBLA in collecting information on individual contracts negotiated between RTCs, blood product users and BPL and on the total output and distribution of NHS-sourced blood products from BPL; they might occasionally need to intervene to challenge the prices of individual contracts, or to impose additional restrictions on BPL eg over arrangements for separating the fractionating of NHS-sourced plasma from other plasma inputs.

> Comment: This model allows the greatest possible devolution of responsibility to regions. Against this, the residual role for CBLA is rather ill-defined and it might be difficult attracting people of sufficient calibre to serve on it. More seriously, it is not clear that RHAs either want or are ready to take on the additional functions, particularly of marketing blood products.

Certainly to begin with there would be a lack of expertise in RTCs which commercial suppliers of blood products would be quick to exploit. And allowing RTCs to market products might distort the normal methods of procuring pharmaceuticals through district pharmacies and would undo the efforts made by BPL in the last two years (with DH encouragement) to market their products directly to districts.

8. On **Model B**, RTCs would sell plasma to BPL which would then market blood products directly to the user units. CBLA would determine the rules which would govern BPL's marketing of NHS-sourced products (eg determining under what conditions, if any, they could market abroad and would either fix the plasma input price or supervise negotiations with individual RTCs as in Model A.

**Comment:** In effect, CBLA would be taking on DH's current role for the oversight of the whole system; otherwise there would be very little change from the status quo. There is still the potential for conflict, in this case between CBLA and BPL rather than as at present between DH and BPL.

9. On **Model C**, RTCs would sell plasma to CBLA which would then contract with BPL to fractionate plasma into blood products. CBLA would then market these products (possibly using BPL as its agent) to the users.

**Comment:** This model gives a clear role to CBLA. As with Model A, it would allow BPL to operate in strictly commercial terms, while allowing BPL's recently-required expertise in marketing to be put to good use. The main difficulty with this model is that it is not clear who would in practice determine the price of plasma. In theory, CBLA as the monopoly buyer would be expected to have greater leverage and this could unduly depress the plasma price. If necessary, DH could arbitrate to set a fair price; or CBLA could be set up so that NHS representatives had the dominant voice which they could use to ensure a fair price.

10. On **Model D**, RTCs would become managerially responsible to a new authority combining the functions of NBTS and CBLA which would then take responsibility for the entire system of blood and blood products. On this variant, fixing the plasma price would become an internal decision for the new authority. Again, one would expect the new authority to be largely owned by the NHS.

> **Comment:** This variant might be thought to go against the grain of the NHS reforms in making RTCs subject to central rather than local control. However, the proposal is for an NHS-controlled (not DH-controlled) body and there are comparable examples elsewhere in the new NHS. Moreover, we understand that such a proposal would have some support from RTCs themselves, and possibly from the NHS more widely.

**Relation of the NBTS Directorate to the CBLA**

11. The Ernst And Young report (executive summary included in the background papers) address the complementary question of the possible role of the NBTS Directorate and its relation to RTCs and to a reconstituted CBLA. A range of options is considered, (see Annex) but the solution advocated would involve the NBTS Directorate and CBLA coming together to form a new contracting authority for both blood and blood products, the "National Blood Authority" (NBA). It is argued that this unified authority

> would be in a stronger position to control quality both of cellular products and of the plasma input to blood products
>
> could achieve a more efficient use of capital resources (eg ensuring that quality control was carried out by a small number of well-equipped centres instead of in each RTC as at present)
>
> could establish uniform costing throughout the NBTS and so help to identify collection systems where costs are unacceptably high.

12. Logically, the decision on the relation of the NBTS Directorate to the CBLA is independent of the particular model chosen for the future role of the CBLA (except that model D necessarily requires the two to be combined). However, if the NBTS Directorate and the CBLA are to come together into a unified authority the relation of the new authority towards RTCs will have to be broadly similar for cellular components and plasma. This implies that under models A and B the new unitary authority would do little more than to oversee the operation of the contracts for supply of cellular products between RTCs and their users, perhaps ensuring on behalf of the latter that quality control and costing procedures were acceptable. On model C the new authority would formally contract with RTCs for the supply of cellular products which it would then supply to end users. (In practice the initial negotiations would probably be between the RTC and users in its "natural " catchment area but the new authority would oversee the national match of supply and demand and could intervene to arrange alternative sources of supply for particular users if for any reason this seemed desirable.) Model D, as already noted, requires the new unitary authority to become managerially responsible for the RTCs.

Suggested issues for discussion

13. Several interacting decisions are required and participants at next week's discussion will wish to range freely over the range of options identified. However, it may help to focus discussion if the following issues are considered in the course of the meeting:

(i) What are the expected benefits to the NHS of the proposed "uncoupling" of CBLA and BPL? Would there be in practice a residual role for CBLA in respect of blood products? Are there any disadvantages to the NHS?

(ii) What benefits would flow from the proposed unification of the NBTS Directorate and CBLA into a "National Blood Authority". Would it work? Are the issues for blood and blood products sufficiently similar? Are there any disadvantages?

(iii) Which of the 4 models described in paras 6-10 would be most suitable for the new "uncoupled" CBLA or for the unified National Blood Authority? Are there any other significant variations which need to be considered?

Department of Health
(Environmental Health and Food Division)
June 1991

**ANNEX**

NBTS: OPTIONS IDENTIFIED IN THE ERNST AND YOUNG REPORT

1. Following the Touche Ross Report, the NBTS Directorate asked Ernst Young to undertake a study to consider whether there is a role for a central organisation in the BTS in the light of changes in the management and organisation of the NHS and possibly in the CBLA.

2. The options which they considered are described below

1) **The Abolition of all Central Functions** (National Directorate and CBLA)

This option would result in no central influence being maintained, leaving the RTCs and BPL without any co-ordinating body.

2) **No change to current practice**

The RTCs would maintain their independent status and the National Directorate its advisory and co-ordinating role.

3) **Franchising**

This option envisages the National Directorate franchising RTCs to collect and process blood within the NBTS. The franchise would only be granted where RTCs met nationally established criteria for safety and quality.

4) CBLA Owns Plasma/Directorate Operates a Franchising System

This builds on the franchise arrangements at 3 but CBLA would own the plasma and use BPL as a contract fractionator.

5) **Licensing Authority**

The National Directorate could take on the role of licensing the RTCs from the Medicines Control Agency. This would require creating the National Directorate as some form of statutory licensing body with concern for quality and safety. However it would not address the issues concerning prices and relationships with CBLA/BPL.

6) **National Body Setting Prices for both Blood and Plasma within the Transfusion Service**

This body would set the prices of red cells, plasma and associated products within the BTS.

7) **Single Contracting Authority**

There would be a united CBLA and Directorate organised as a National Blood Authority which would contract with RTCs for the supply of blood and plasma and with BPL or other manufacturers for the contract manufacture and marketing of blood products. The RTCs would continue to be managed separately.

8) **Direct Management**

This option involves the RTCs coming under a central management body. Model D above also covers this option.

POLICY - IN - CONFIDENCE

**Background to the Touche Ross and Ernst and Young Reports on the Future Options for the CBLA and NBTS**

1. The Central Blood Laboratories' Authority (CBLA) commissioned a study by the consultants, Touche Ross, to consider the future role and objectives of the organisation, to assess the prospects for its manufacturing arm, the Bio Products Laboratory (BPL) and to examine suitable status options for each organisation.

2. The essential background information and key recommendations from the study are contained in Annex A. The study gave rise to the idea of "uncoupling" BPL and the CBLA so that the former could concentrate on operating as efficiently as possible while the CBLA acted as "guardian" of the freely donated plasma. The report also raised questions about the relationship between the CBLA and the NBTS and the organisation of the blood services.

3. Following the Touche Ross report the NBTS Directorate asked Ernst and Young to investigate whether following the NHS reforms, there was a role for a central organisation in the Blood Transfusion Service and to consider the organisational options for carrying out any such actual activities. The executive summary of the consultants report is at Annex B.

4. The NBTS Directorate supports the conclusions and recommendations made by Ernst and Young. Annex C sets out the CBLA Chairman's supporting view.

## 2. BACKGROUND

### 2.1 Responsibility for the Provision of Plasma Products to the NHS

The collection of whole blood and its separation into plasma and cellular components is the responsibility of 14 Regional Transfusion Centres (RTCs), each responsible to a Regional Health Authority (RHA). The RTCs are nominally part of the National Blood Transfusion Service (NBTS) which is co-ordinated by a National Director, but this position carries no executive authority over the RTCs.

The CBLA was created as a Special Health Authority (SHA) in 1982. Statutory Instrument no.1515 defines its functions as:

- provision of laboratories for the manufacture of blood products and other purposes;
- preparation of plasma fractions for therapeutic, diagnostic and other purposes;
- research and development of plasma protein fractionation and for other purposes;
- the manufacture of blood grouping reagents and other related reagents.

The CBLA is comprised of two bodies: the Bio Products Laboratory, (BPL) which carries out the defined functions and the International Blood Group Reference Laboratory (IBGRL) which operates a research and reference laboratory as a diagnostic and support service for the NHS and the WHO, and for "other purposes" within the above definition.

BPL

BPL is comprised of two manufacturing divisions:

- Therapeutics, which manufactures plasma protein fractions. Its products can be classified into three main groups: albumin, coagulants such as Factor VIII, and immunoglobulins. In 1989/90 sales of therapeutic products amounted to £32.8 million and are strongly rising;
- Diagnostics; (BPL(D)), which manufactures blood typing and diagnostic reagents. The majority of these are now produced by monoclonal techniques. In 1989/90 sales amounted to £1.2 million.

In the 1989/90, 97 per cent of BPL's sales were to the NHS, the remainder being accounted for by sales overseas and to the private sector.

Touche Ross

### 2.2.3 Definition of Self Sufficiency

Since the World Health Assembly of 1975, it has been accepted that national self sufficiency in blood and blood products is desirable on the grounds of both quality assurance and strategic safety.

This policy was determined at a time when the product collected from blood donations was similar to that which was transfused: that is, transfusions tended to be of whole blood, red blood cells or plasma. The manufacture and increasing use of specific cellular fractions and plasma protein fractions has transformed transfusion medicine. As a consequence, two distinct interpretations of national self-sufficiency have emerged. The first is the original concept of national need which applies to whole blood and cellular products and to the plasma fractionated by BPL. The more recent interpretation is that of clinical requirement relating to plasma products. This means that if clinicians consciously prescribe non-BPL plasma products, clinical demand for BPL's products will be less than national need. The difference in interpretation is exacerbated by the introduction of charges for BPL's products and explicit recognition of the freedom of clinicians to prescribe their products of choice. In Scotland, self-sufficiency continues to be interpreted as national requirement for both whole blood and all plasma proteins.

The impact on BPL of this DoH interpretation of self-sufficiency is that:

- it is restricted to taking plasma from RTCs at the quality, volume and price they offer. This inevitably constrains the options available to BPL to improve its cost-competitiveness. There may be scope for some flexibility in negotiation on this however, and we discuss this in Section 4. It should be noted, however, that the commitment to voluntary donor supply means that, in current circumstances, there are few, reliable alternative sources of plasma available;

- whilst DoH remains committed to RTCs as providers of blood in accordance with the original policy of self-sufficiency, the modified interpretation by DoH of plasma product self-sufficiency, means there could be little requirement for UK plasma if BPL lost significant market share to imports;

- clinical freedom, delegated budgets and charges for BPL's products mean that BPL's products may not necessarily be the products of choice. BPL does recognise the increasingly competitive market in which it operates. It is faced with an increasing number of customers with both pharmacists and clinicians involved in the purchase decision. The marketing challenge which arises will assume increasing importance in the future. The price, as well as quality, of BPL's products as compared to those of its competitors will be key factors in purchasing decisions.

## 2.3 Changes in the Market for Plasma Products

The volume of plasma currently required by BPL is driven by demand for Factor VIII. The fractionation process means that some products such as albumin can be produced in excess of national requirements. This is not confined to BPL and all fractionators, whether 'not-for profit', or commercial, appear to be faced with this situation. The outcome is increasing price competition for those products where surpluses may be produced. Past experience suggests, however, that this tends to be cyclical.

The availability of new higher purity products is the second development of note. These can significantly improve the quality of life of some haemophiliacs. High purity products are likely to take an increasing share of the market in the future even at significantly higher prices than existing products. BPL has developed its product range in response to this.

Perhaps the most significant change in plasma products manufacture is the development of recombinant techniques which enable synthesis of plasma fractions without the use of human derived plasma. Fears about viral transmissions and adverse reactions in the wake of HIV transmissions to haemophiliacs have heightened clinicians' awareness of product safety and these products are likely to be perceived as safer than plasma derived equivalents. The market share of recombinants will depend on the interplay of price and of the proven safety of high purity plasma derived products.

Touche Ross

## 2.4 The European Community Dimension

In 1989, the Council of Ministers approved a Directive on Pharmaceutical products which included clauses on blood and blood products. Directive 89/381 contains mandatory and non-mandatory requirements. The key points are:

- from 1st January 1992, plasma derived products will be classed as pharmaceutical products and will be required to hold appropriate licenses. This clause will be mandatory;

- within the overall target of Community wide self-sufficiency Member States will be required to move towards national self-sufficiency in blood and blood products, collected from voluntary unpaid donors.

The EC Directive may influence competitive positioning in the plasma fractionation industry. If deficit countries invest in voluntary donor programmes, there may be opportunities for BPL to offer contract fractionation to these countries. However, this element of the Directive is not binding, and whilst there may be some movement towards its target, full compliance with national self-sufficiency in voluntary donated plasma is unlikely.

Consistent pressure on RTCs to improve the quality of product supplied should be maintained. We were told that the NBTS has recently introduced a quality programme including peer review of the RTCs. BPL was involved in one of these audits and could seek to widen its involvement in this process. We understand, however, that another RTC has refused BPL access to the RTC's facilities or to supply BPL with data. It is too early to make an assessment of the results of this quality initiative, but it may go some way towards achieving quality and consistency.

There are two aspects of quality monitoring. Firstly BPL as a Product License holder will be held responsible for the quality of input material. BPL has to satisfy itself that quality standards are being met. It can ultimately seek to do this directly, for example by making the sort of inspection arrangements that a commercial organisation would enter into with a supplier. Secondly, although separated white cells and other, non plasma, derivatives will not be defined as pharmaceutical products so RTCs will not be required to hold Product Licenses it is desirable that RTCs be subject to GMP accreditation and inspection by the Medicines Control Agency (MCA). The SNBTS is already seeking to license its RTCs and the DoH indicated to us that it intends to establish a "Special Licensing" requirement for RTCs in England and Wales.

Opinions were polarised as to the MCA's ability to conduct regular, informative and supportive inspections: some felt the MCA lacked resources, whilst others found the MCA very helpful and good value. However, this will not exempt BPL from its responsibilities on raw material supply.

It is too soon to assess the likely impact of either the NBTS peer review programme or MCA licensing of RTCs. BPL should explore with the NBTS and the DoH how monitoring and quality assurance in the RTCs can be best achieved. We return to this matter in Section 4.

Given that BPL, as the product licence holder, is ultimately responsible for quality and that input quality is an important determinant of yield and cost, BPL may need to seek its own arrangements with individual RTCs. One option which BPL should actively explore is to take increased supplies of a particular quality plasma from one or more RTCs who are particularly good at obtaining them. This option was recommended by the Wilson Committee's Organisational Study of the NBTS in England and

Analysis of BPL's operating costs demonstrates that increased throughput of plasma could enable BPL to reduce its unit costs considerably. For example, a volume increase of 250 tonnes from current output levels could achieve the following reductions in unit manufacturing costs:

- Factor VIII: 28 per cent;
- Factor IX: 31 per cent;
- Normal IgGs: 23 per cent;
- Albumin: 39 per cent.

(Note: These figures exclude the purchase of plasma and assume an increase in staff numbers of 10 per cent and the introduction of a shift system of working).

Some RTCs have claimed they could increase the amount of plasma supplied. The NBTS Director indicated that this could amount to a 20 per cent increase over current volumes and that up to one-half of this amount could be achieved from improved separation rather than increasing plasma collection from the population.

Sales

Currently BPL takes all the plasma produced by the RTCs. This volume is required to meet demand for NHS Factor VIII. We noted earlier that this level of throughput generates an excess over clinical demand for some products. BPL could improve its revenue position by seeking new markets for these products.

To date, there has been some uncertainty about the DoH's position on BPL selling excess products abroad, but it is likely that it will not object to sales which fulfil the following criteria:

- they are produced as surplus to national requirements;
- surplus production has not involved supply of additional voluntary donated plasma over and above that required for NHS needs.

## 4.4 Future Role of CBLA

If CBLA is successful in achieving within the NHS the status and commercial freedoms BPL needs to pursue its strategy, and relationships between BPL and the RTCs are put on a "normal" commercial basis as between a customer and its suppliers, then there is no obvious independent role for CBLA. If BPL were a Trust in these circumstances, CBLA could cease to exist and IBGRL could report elsewhere. If BPL were to become a private sector contract fractionator then CBLA may need to continue in being, to ensure that the contractual arrangements were working to the benefit of the NHS. Its prime task would be to 'own' the plasma 'gift' on behalf of the NHS having contracted its processing and marketing to BPL.

However, it may be possible for the contract to be supervised by a broader-based NHS Authority, which would absorb the residual CBLA role.

A major concern, however, of both BPL management and the CBLA, is that it may be sometime before the internal market for blood products in the NHS works smoothly. The central question for BPL is whether the RTCs are in practice capable of delivering the plasma it needs of the right quality, in the volume required, and at a price reflecting market forces. The DoH, NBTS and individual RTCs are all looking at ways to improve performance, and the removal of Crown Immunity will give the MCA a specific role in licensing some of the manufacturing activity of the RTCs. BPL is understandably concerned however, that the improvement it seeks may take time to achieve and that RTCs may have difficulty obtaining the investment necessary for improved performance.

Until these matters are resolved it is important that CBLA maintains a role beyond the supervision of BPL's trading activity in order to ensure the blood products market develops in the way DoH intends. Structural change may even be required in order to ensure that NHS patients are served efficiently and effectively. We should note in this context that an alternative model to the "internal market" approach of England and Wales is that of the vertically integrated Scottish approach.

In Scotland, blood and plasma procurement and plasma fractionation are carried out by a single body: the Scottish National Blood Transfusion Service (SNBTS). The SNBTS is accountable to the Common Services Agency (CSA) which in turn reports to the Scottish Home and Health Department. There is free movement of blood products between the RTCs, no cross accounting for plasma and plasma products and the products are supplied to the NHS free of charge and consequently no competition.

## 5.2 Future Status

In view of the arguments we have outlined above, and our analysis to date, our key recommendations are as follows:

- in the short term at least, BPL should retain its position within the NHS, within the umbrella of CBLA's SHA status, and focus on improving its operating efficiency, developing appropriate commercial relationships with the RTCs, and on negotiations with the DoH to achieve those freedoms which are critical to its strategic objectives. Opting for Trust status would not increase its commercial freedom per se, but could help to create commercial ethos within the organisation;

- in the medium term if it proves difficult to achieve the desired freedoms through negotiation, CBLA will need to consider alternative status options for BPL outside of the NHS. The best option in these circumstances could be to seek some form of joint venture with a commercial company which included both fractionation and supply of recombinant products;

- CBLA needs to ensure that the blood and plasma product market develops in the way the DoH intends. We understand that NBTS is seeking SHA status, and if successful may be able to ensure that arrangements between BPL and the RTCs are put on an effective commercial basis. In those circumstances CBLA may have no longer term role. BPL could operate independently as a Trust. If BPL moved into the private sector, supervision of the contractual arrangement with the NHS would be necessary. CBLA could do this initially but this role could be passed on to another NHS body, for example, NBTS. In the event of CBLA no longer having a role in respect of BPL it would make sense for IGBRL to report to another organisation such as an NBTS which was an SHA.

# MANAGEMENT SUMMARY

1. Major and fundamental changes are being made to the management and organisation of the National Health Service. Given the unique nature of the National Blood Transfusion Service and its strategic importance to the NHS as a whole, it was important to consider how these changes were likely to affect the NBTS and, in particular, to investigate whether there is a role for a central organisation for the BTS. Ernst & Young were commissioned by the National Directorate of the NBTS to study these issues.

2. We undertook the study with no pre-formed ideas as to the need for or the nature of a central organisation for the NBTS. Instead we began by considering, with BTS management and other interested parties, the key relationships within the blood transfusion framework:

- those with donors
- those with purchasers
- those with fractionators of plasma
- those between Regional Transfusion Centres

3. From this we identified a number of key activities which it was essential or cost-beneficial to be carried out centrally. The most significant of these were:

- the maintenance of donor confidence through nationwide donor selection standards
- the presentation of an attractive and coherent image of the BTS to donors
- the need, through accurate comparisons of performance and promotion of best practice, to ensure a cost-effective service for purchasers
- the need, through quality audits which complement the work of the Medicines Inspectorate, to guarantee a consistently high quality product for purchasers
- the critical requirement to address the provision of blood and its products in a comprehensive way; recognising, and taking into account for the benefit of the NHS as a whole, the cost relationships which exist between plasma on the one hand and cellular products on the other
- the need for cost-effective mechanisms to balance local short term supply and demand variations
- the need for longer term planning regarding the size, shape and nature of the BTS

4. We described a range of eight possible organisational arrangements through which the above requirements could be met and measured each of them against four key criteria:

- the effects which they would have on the confidence of donors

- the extent to which they would create a coherent and comprehensive service meeting the needs of purchasers and the NHS as a whole

- the level of competition which they would introduce into the NBTS

- the authority or "clout" which they would provide to ensure that, where necessary, central decisions were implemented locally

5. Resulting from this review we identified two possible arrangements which met the criteria and would deliver the required range of activities:

- A Central Contracting Authority (a unified National Directorate and CBLA) which would obtain cellular compnents and plasma from Regional Centres. This would remove the current artificial separation of responsibility between these two aspects of whole blood. The Contracting Authority would establish competitive contracts with Regional Centres, and perhaps non-BTS suppliers, in order to meet the NHS requirement for blood and plasma as economically as possible. The new authority would additionally contract with fractionators to ensure that the plasma was used effectively to meet NHS needs. Regional Centres would remain managerially independent of the central Contracting Authority.

- A Centrally Managed Service with direct line management reporting from the head of a central authority to Regional Transfusion Directors This authority would combine and extend the current functions of the National Directorate and the CBLA. With careful management the links between RTCs and their Regional users could be maintained whilst developing coherent national policies.

6. We considered that both options offered advantages in terms of qualitative benefits but that the Contracting Authority introduced an element of competition into the BTS Framework.

7. We did not consider that a "No Change" option would meet our criteria; nevertheless, we compared the financial costs and benefits of these two options with those flowing from "No Change". We concluded that the staffing, systems and set-up costs of both options exceeded those of "No Change" but that those of the Central Contracting Authority were very much lower than those of the Centrally Managed Service under all three headings.

8. We identified substantial scope for financial savings from both options - very little of which could be expected to be realised through "No Change". We are confident that these savings would, on a year-on-year basis, more than meet the costs of the establishment and maintenance of a central authority.

9. Based on this analysis we conclude that there are strong financial and qualitative arguments in favour of the creation of a new unified central authority for the NBTS and CBLA and that, based on financial cost/benefits, the most appropriate form for this body to take is the central Contracting Authority described above.

10. We therefore recommend that a Contracting Authority is the most appropriate central organisational arrangement for the Blood Transfusion Service and that early action should be taken to investigate the precise means and timetable for its introduction.

Section II

Annex C

NBTS Proposal for CBLA/NBTS to merge to form a

NATIONAL BLOOD AUTHORITY

3. The proposal for the formation of a N.B.A based primarily as a policy and contracting authority with both fractionator processors (eg BPL) and the RTC's for collection and supply has significant merit. This should ensure that the criteria of self sufficiency can be achieved economically whilst establishing consistent and high quality standards. The Authority will need to give the assurance of comprehensive service and quality to patient care and to the protection of donors and their "gift" to the NHS.

This should ensure that current operating costs will fall and that new economic technologies can be introduced rationally and the following reference criteria will apply to the Authority.

3.1 To effectively optimise the collection and utilisation of human donor blood and its components, cells and plasma to meet the criterion of UK self sufficiency economically at local and national level, whilst avoiding waste and without excessive contributions from UK unpaid volunteer donors.

3.2 To be accountable for the establishment and consistent application of effective ethical and quality standards to co-ordinate research and development activities and ensure relevant state of the art technology is consistently utilised, and assure both donors and recipient patients of the high safety standards employed. Ensure participation at appropriate European and International (incl. WHO) institutions. Be responsible for special laboratories as necessary, eg. IBGRL.

3.3 To establish common accounting and information, systems, practices and policies. Appraise the demand on and economic functioning of the service and thus establish firm volume and price contracts for collection of blood, blood components and plasma from RTC's and placing contracts for fractionation and processing as required.

3.4 To establish a national investment policy in concert with the service and agree rational and economic capital investment programmes avoiding duplication or the creation of excessive capacity or resource.

3.5 To ensure a proper flow of information to Ministers, Regions and interested parties, and promote recruitment of blood donors as agreed on a local and national basis.

This methodology will allow maximum local flexibility and accountability whilst ensuring national policies and requirements for the products, within self sufficiency criteria, are met. Also to determine that safety, quality and economy are efficiently and ethically met so that all parties may be reassured and protected.