Management in Confidence
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THE NATIONAL BLOOD TRANSFUSION SERVICE IN ENGLAND AND WALES: AN ORGANISATIONAL STUDY

A report by

NHS Management Consultancy Services

MANAGEMENT-IN-CONFIDENCE

THE NATIONAL BLOOD TRANSFUSION SERVICE IN ENGLAND AND WALES:

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NHS MANAGEMENT CONSULTANCY SERVICES

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NHS MCS STUDY OF THE NATIONAL BLOOD TRANSFUSION SERVICE IN ENGLAND AND WALES

SYNOPSIS

1. The study was commissioned against a backcloth of:

1.1 the requirement for England and Wales to become self sufficient in blood products and thus the necessity to ensure adequate supplies of plasma for the CBLA fractionation plant at Elstree;

1.2 the problem of the imbalance between supply and demand for blood and components which is in essence that some London regions are unable to meet, from within their own collection arrangements, the requirements of their hospitals and rely to some extent on supplements from provincial regions and Scotland;

1.3 the recognition that the National Blood Transfusion Service is in reality a loosely federated collection of Regional Transfusion Centres and as such might not be ideally organised to cope with the strains that the factors identified at 1.1 and 1.2 place on it.

2. Our examination and discussions lead us to conclude that nationally there is an adequate supply of blood available or potentially available to meet the dual demands of the plasma requirement and hospital needs for the present and foreseeable future. The major question to be addressed is therefore whether the BTS is organised in the best way to maximise the available potential. We have discovered wide variations in policy, procedures and functions between the regional transfusion centres with no real evaluation of performance and little effective co-ordination either between the regional centres or between the centres and CBLA.

3. We conclude that there are four underlying problems confronting the BTS, these are:

3.1 the absence of reliable management information;

3.2 the inability of two London regions to meet the needs of their hospitals from within their existing collection programmes;

3.3 the absence of co-ordination between individual RTCs and also between the BTS (the collective RTCs) and CBLA.

3.4 arising from 3.1 and 3.3 apparent inefficiencies both within and between individual RTCs.

4. In our view the absence of management information should be addressed as a matter of priority. We therefore recommend the introduction of a uniform system across the BTS to provide the basis for more effective management regardless of whatever decisions are made in relation to overall organisation. In order to ensure both priority and uniformity we recommend that this should be a central initiative.

5. On the question of organisation we suggest that there are 3 options available for the future of the BTS. The implementation of the recommended information system is crucial to each. Briefly the options are:

5.1 The introduction of reliable management information which will provide the tools to enable Regional General Management to evaluate and question the performance of the BTS. This coupled with continuing financial constraints will generate the evolution of a more effective and possibly more co-ordinated BTS and thus organisational change will not be necessary.

5.2 The option at 5.1 does not address the question of the relationship between CBLA and the BTS nor guarantee greater co-ordination between regions. Hence the second option seeks to tackle this by raising the profile of the existing Regional Transfusion Directors Committee and the Advisory Committee on the Blood Transfusion Service and by introducing a new co-ordinating committee for CBLA and the BTS. Under this option the committees would have no executive power as this option envisages that the BTS would remain a regionally managed and funded service. However by formalising the role of the committees it is suggested that greater cognisance may be taken of their views and decisions.

5.3 The third option is the creation of a special health authority to centrally manage and fund the BTS. The authority could also be responsible for CBLA if this were considered appropriate. A National Director would be appointed with a back up organisation. The existing regional transfusion directors would be accountable to the National Director.

6. The report outlines the strengths and weaknesses of each option and recognises that radical change at this time may be considered precipitate. We suggest therefore that a composite approach - broadly to install the information system and establish the RTC/CBLA co-ordinating committee - offers a fourth option. This would enable major change to be held in abeyance and considered in the light of the data generated by the information system and any reform which may have evolved as a result of its introduction.

7. We suggest that there is potential for savings from improving effectiveness and co-ordination in the BTS. The questionable accuracy of available costing information requires that any assessment of savings which is based on current data be treated with great caution. With that caveat current data indicates savings of the order of £6 to £16 million may be available. An accurate and realistic assessment of potential savings will have to await the introduction of the recommended management information system. Any savings identified are theoretically achievable under each of the options subject to the proviso that the information system is implemented uniformly and the information it generates acted on. The rate of achievement of any savings may however vary depending on which organisational structure is adopted. Broadly in our view it is reasonable to suggest that the rate of achievement will probably be slowest under option 1 and most rapid under option 3.

8. Apart from the rate at which the proposed organisations can achieve any potential savings we must also consider their ability to do so. Whilst it is clear that there are no organisational barriers to prevent a centrally managed BTS from doing so this is not so certain if management were left with the Regions. It is not realistic to expect each RHA to attach the same degree of priority to reviewing the operation of it's RTC. The savings, whilst significant when viewed globally, are in reality a fairly small proportion of each RHA's budget so that their achievement may have less urgency for the RHA than other areas. We have to conclude that there would be considerably less certainty of attaining the full potential savings within the BTS if it continued to be regionally managed.

1. INTRODUCTION AND BACKGROUND TO STUDY

1.1 There have been a number of developments in recent years including advances in medical care, blood component therapy, and, in line with the advice from the World Health Organisation, the requirement for England and Wales to become self sufficient in blood products. These have led to an increase in demand for blood and blood products.

1.2 These developments have had an impact on the ability of the existing Blood Transfusion Service (BTS) to respond to the needs of hospitals and the requirements of the new Blood Products Laboratory (BPL) for plasma for fractionation. There was concern within DHSS, Regional Health Authorities (RHAs) and the BTS as to whether the organisation, funding and management of the existing BTS was appropriate to the changed circumstances. It was therefore decided that DHSS should sponsor a study, to be undertaken by NHS Management Consultancy Services with the following terms of reference:

1. To examine the blood transfusion service and related services provided by Regional Transfusion Centres and the Central Blood Laboratories Authority in order to:

   a. assess the current and forecast needs of the NHS and private sector for such services;

   b. identify those services in which Regional Transfusion Centres can or cannot be expected to be self sufficient; and

   c. identify the way in which Regional Transfusion Centres and the Central Blood Laboratories Authority interact.

2. To advise on how supply and demand for blood and blood components (and activities relating to them) in individual regions can best be reconciled and co-ordinated to meet Regional, Supra-Regional needs, and ensure a cost effective service; and whether financial and organisational changes are needed.

3. To report.

1.3 A Steering Group chaired by Mr G Wilson, a member of the Central Blood Laboratories Authority (CBLA) and Bradford DHA was set up to oversee the conduct of the study. Other members:

Mr T Binns - District Treasurer - Barnet DHA

Dr R Finney - Consultant Haematologist, North Tees General Hospital.

Dr I Fraser - Chairman of the Regional Transfusion Directors Committee and Medical Director of South Western RTC.

Mr M Harris - Assistant Secretary, Branch HSI, DHSS.

Mr R Nicholls - District General Manager - Southmead DHA.

Professor J Scott - Regional Medical Officer - Trent Regional Health Authority.

The Secretariat:

Mr M H Arthur)
Dr R Moore) DHSS
Dr A Smithies)

The steering group met four times to receive progress reports from the assignment team and also to comment on the draft report.

Methodology

1.4 Basic factual and statistical data was obtained from Regional Transfusion Centres (RTCs) by questionnaire. The team visited each RTC and the Central Blood Laboratories Authority (CBLA) at Elstree and Oxford. During each visit discussions were held with key personnel and, where requested, with local trades union representatives. In each region views were sought from Regional and District Health Authority officers who are involved with the BTS and from medical and scientific staff at two hospitals, including in one region a private hospital. Views were also obtained from the Royal College of Pathologists. The study was limited to an examination of the service in England and Wales but a visit was made to the Scottish National Blood Transfusion Service to compare the organisational arrangements.

1.5 In the report we discuss how RTCs go about the common tasks of collecting, testing, processing and distributing blood. We also examine the other key areas relating to the BTS. The variations in organisation and operational practices and pressures which exist mean that comparison which is based solely on available statistics is misleading because of ambiguities in definition. We therefore detail and discuss the variations and illustrate these and the effects thereof with statistical evidence. Much of what is said will come as no surprise to anyone familiar with the working of the NBTS. We would emphasize that it is not our aim to make direct comparisons between centres for the purpose of either criticism or praise. To that end individual RTCs are generally not identified. Where comparisons are made between centres these are usually to illustrate the wide variations in the way common tasks are tackled. We attempt to identify and explain variations in terms of physical, demographic or other factors. Where this is not possible we suggest the variations may be significant in considering organisational options for the future.

Acknowledgements

1.6 The team are grateful to all those in the Blood Transfusion Service and the NHS generally who gave generously of their time, co-operation and expertise during the course of the study.

Summary of findings

1.7 We conclude that the absence of reliable management information impedes the effective management and development of the BTS and we recommend the establishment of a uniform management information system (MIS). We present three organisational options for the future of the BTS within which the MIS could function. We suggest that there is scope for considerable saving from greater co-ordination and that the achievement of such savings and the rate of achievement depends to a great extent on the organisational structure which is adopted.

2. THE PRESENT STRUCTURE

Organisation

2.1 The constituent parts of what is widely, but falsely, assumed to be a National Blood Transfusion Service are independent Regional Transfusion Centres and a Special Health Authority (SHA) - the Central Blood Laboratories Authority. CBLA operate the Blood Products Laboratory (BPL) which is the plasma fractionation plant producing therapeutic and diagnostic products and the Blood Group Reference Laboratory (BGRL) the national reference laboratory for blood grouping and other serological problems. Each RTC is accountable to its Regional Health Authority and is managed by a Medical Director (known as the Regional Transfusion Director - RTD) of consultant grade. The management of CBLA is vested in the SHA and exercised via a Chief Executive. Scotland and Northern Ireland have completely separate arrangements.

2.2 The RTDs meet regularly at the Regional Transfusion Directors Committee, which provides the major vehicle for discussion of common problems and developments. The Chief Executive of CBLA and the Directors of BPL and BGRL have a standing invitation to attend these meetings. Beneath this committee the BTS has formed itself into three geographical divisions with regular meetings of directors and medical staff within these divisions. In addition there are a series of committees covering the various disciplines within the BTS eg Administration, Donor Organisation, Scientific and Technical Services etc. None of the committees, including the RTD's committee, has any formal authority or executive power and there is no requirement for RHAs or individual RTDs to act on decisions which may be taken by the various committees.

2.3 DHSS - Branches HSI and MED SEB - has policy responsibility for the BTS but no operational responsibility beyond the overall accountability of the Secretary of State. To assist in it's policy role the Department may call upon the advice of the Advisory Committee on the NBTS - a multi-disciplinary body which has a purely advisory ("sounding board") role. In addition the Chief Medical Officer has a Consultant Adviser on Transfusion, a position currently held by the RTD for North Western Region.

2.4 Each Region is served by an RTC but the boundaries of the areas served by the centres are not co-terminus with existing RHA boundaries; they relate generally to earlier NHS Health Authority boundaries. The needs of the South

East Thames (SET) and South West Thames (SWT) RHAs are served primarily from the South London Transfusion Centre situated at Tooting which the two RHAs fund jointly. SETRHA also funds a small centre in its region at Lewisham which is completely independent of Tooting. It is not generally recognised in the Transfusion world as independent although it offers almost the full range of services provided by other RTCs. The North Western RHA operates two centres under one RTD in its region. Several other RTCs have sub depots/offices elsewhere in their regions for one or a range of functions.

2.5 Each RTC is structured in broadly the same way although there are considerable variations on the main theme. Reporting to the medical director are the heads of administration, scientific and technical services, donor organisation and nursing. Each of these individuals heads a sub structure of departments and functions.

Management

2.6 As RHA structures vary so do the ways in which the RTCs fit into the regional management structure. Generally the RTDs are accountable to either the Regional Medical Officer or a senior officer of the RHA with responsibility for one or more of a range of regional services. In Wales the arrangements are somewhat different. Cardiff RTC provides a regional service for South Wales. The Welsh Office has devolved line management to a DHA whilst retaining overall authority on strategic matters. North Wales forms part of the Mersey RTC's catchment area and the Welsh Office has no involvement in the BTS service to that area.

2.7 The extent to which the region or district takes an active role in the affairs of the centre varies. We have seen examples of quite direct management via a committee of RHA and RTC officers and, at the other extreme, situations where the director is, to all intents and purposes, given a free hand in the running of the RTC. In the past regions have generally taken little active interest in the management of their RTC. The indications are that recently this situation has started to change due to a combination of factors such as financial constraints and the introduction of general management. More directors are now being asked to account for and justify RTC activities. Accountability has been made difficult for all parties by the general absence of meaningful and uniform statistical and costing information.

2.8 Until recently operational responsibility for CBLA laboratories had been delegated to the directors of BPL and BGRL. During the course of the study the structure of the organisation was changed. Firstly reagent production became part of BPL, was renamed BPL Diagnostics and put under the operational command of the Director of BPL. Secondly a new directorship of financial and administrative services was created. A Chief Executive has been appointed to whom the directors of the re-structured organisation are accountable. The Chief Executive is directly accountable to CBLA for the running of both BGRL and BPL.

2.9 The chairman and members of CBLA are responsible to the Department for the performance of the laboratories, within the broad policy guidelines set by the Department, through the normal NHS accountability review process.

Funding

2.10 The level of funding of each RTC is determined separately by the RHA in accordance with the financial planning mechanisms it employs. The 85/86 budget for the BTS in England and Wales, excluding CBLA, amounted to nearly £58 million, ranging in individual RTCs from £2.6 to £6.3 million. Table 1 (page 146) shows each region's total and per capita expenditure in 1985/86. The different level of spending by RHAs is in part related to the different size of populations served. However, even if per capita spending is examined the figures are not strictly comparable. This is due in part to a variation in the range of functions carried out at RTCs as well as differences in funding arrangements. For example some regions choose to fund the purchase of Factor VIII via the RTC while others fund hospitals directly for it. Some RTCs operate a routine regional antenatal service whereas others provide a reference antenatal service only. Similar constraints apply in attempting to compare funding in England and Wales with that of Scotland.

2.11 The attitude of Regions towards the funding of the transfusion effort varies. Many of the RTDs felt that their centres were under-resourced in personnel, premises and equipment. Some regions took a compliant attitude towards the RTC and tended to meet most requests for money. Others regarded the RTC as a competing priority which had to take its share of regional belt tightening. Yet others, for a range of reasons, felt that in the past the RTC had been treated generously and thus should now be a target for economy. To

an extent the attitudes of RHAs were influenced by their perception of their self-sufficiency requirements for plasma and Factor VIII (discussed further in chapter 6). They are also influenced by the ability of the region to adequately satisfy its hospitals demand for blood. In general, as with the attitudes towards management, the indications are that regions are starting to take a greater interest in the question of the financial control of RTCs.

2.12 The revenue budget of CBLA was £10 million in 1986/87. Separate from this is the expenditure on the new fractionation plant at Elstree. As an SHA CBLA is funded from the HCHS vote and competes for funding with other Health Authorities. Budget proposals are prepared within the organisation. They are submitted, via the Chief Executive, to the Authority and then to the Department which determines the eventual level of funding.

RTC Functions

2.13 There is no comprehensive and common definition of what the functions of an RTC are or should be. There is a range of "core" functions common to all centres namely:

2.13.1 collecting blood;
2.13.2 testing the blood collected (for HIV, Hepatitis B and Syphilis);
2.13.3 separating blood into components and freezing harvested plasma for transmission to BPL for fractionation;
2.13.4 issuing blood and products to hospitals;
2.13.5 providing a reference service to hospitals on grouping problems;
2.13.6 providing a source of medical advice on transfusion and product related problems.

Within these functions there are differences in policy, procedures and organisation which are discussed in subsequent paragraphs.

2.14 In addition to these activities there are a range of other functions which have developed in all centres to a greater or lesser extent eg plasmapheresis, production of reagents, research and development, microbiological testing regimes, quality control and tissue typing. There are also functions which have developed in some centres and not others eg ante-natal testing.

2.15 The functional development of the RTCs seems largely to have been the result of individual directors pursuing particular interests and responding to particular demands or pressures, rather than a process of national or regional strategic planning or service development. Some peripheral functions might be termed "regional services" in that they have to be provided by the RHA, eg Tissue Typing and Antenatal testing. However, not all regions have chosen to provide those services at the RTC and others have chosen to provide only part of the service there.

2.16 It is therefore fair to say that neither the treatment of donors nor the service provided to hospitals is uniform across England and Wales. Whether this situation is acceptable is a question that has to be addressed in any consideration of the organisational structure of the BTS.

Staffing

2.17 In addition to variety in the range of functions the centres vary in size. The total staff employed in the BTS is slightly in excess of 3500. Staff employed in each region ranges from 160-400 and the number of donations per annum collected ranges from 86,000 to 258,513. Table 2 (page 147) shows the staff employed in the BTS broken down by region and function and the number of donations collected in 1985/86. We have been unable to establish any correlation between the tasks undertaken and the number and grades of staff employed to undertake them. This is perhaps best illustrated by the following examples:

2.17.1 the largest regional centre in terms of donations collected employs 3 consultants as does the smallest;

2.17.2 on the blood collection front, the variation from the mean of donations collected per Donor Attendant ranges from +30% to -28% a range of 58%;

2.17.3 on the scientific and technical front the variation in the mean of the number of donations dealt with per member of staff in microbiology labs, (basically the testing of donations) ranges from +40% to -30% a range of 70%;

2.18 Increases or decreases in staff numbers in RTCs are seldom assessed in terms of quantified workloads and centres employ varying numbers and grades of staff to undertake broadly identical tasks. Comparison is made difficult because of the absence of any meaningful, objective and common data baselines. We expand on this issue in subsequent chapters and this is, in our view, an issue which needs to be addressed urgently.

3. DONOR ORGANISATION

3.1 The starting point for the RTC operation is the Donor Organisation Department which is headed by the Regional Donor Organiser (RDO). This Department is responsible for drawing up a plan for donor sessions throughout the catchment area. The aim is to ensure a regular flow of blood into the RTC sufficient to meet the predicted needs of the Region's hospitals and also the Region's plasma quota.

3.2 In the majority of Regions the RDO reports directly to the RTD; in the rest the line of responsibility is via the administrator. The RDO is generally responsible for the recruitment of donors; arrangement of donor sessions; calling of donors; publicity; and liaison with voluntary bodies and helpers. The grade of the RDO varies between A & C Scale 9 and 18 not necessarily in accordance with the scale of operations.

Session Planning

3.3 The RDO usually has a target, formal or informal, expressed either as the number of donations required per week, or the number of sessions to be held per week. This target is either determined by the Medical Director, or management team where such exists. From this the RDO will evolve the sessions plan, normally working up to a year ahead. The need for long-term planning is dictated by the necessity to book donation session locations well ahead of the time they will be required. All the RDOs made the point that village halls, community centres, etc, are far more used than in the past and early booking is needed to ensure their availability.

3.4 Planning of the sessions programme is primarily historical, ie the plan for the same period of the preceding year is consulted for an indication of where to go this year. A major constraint is the practice of bleeding donors twice a year. Thus, for example, a panel that was bled the previous January cannot be bled before the following June/July and whilst it can theoretically be bled anytime after that regular donors become used to giving at certain times of the year so RDOs try to stick to these. We understand however that one centre bleeds some of its donors three times in a twelve month period.

3.5 Apart from the above constraint the RDO needs to have regard to a number of other factors. He/she may need to ensure that for example:

3.5.1 there are morning sessions within a certain distance of the centre each day so that blood is available early for platelet production;

3.5.2 the staff travelling time or overnight stays that may be involved is considered. Some centres do not need, or will not allow, sessions that require staff to stay overnight in a particular location;

3.5.3 where teams are decentralised there will need to be sufficient sessions per day within that geographical area;

3.5.4 account is taken of any regular sessions held. Large centres of population will often have regular sessions, sometimes daily.

3.6 There are two main types of session, industrial/commercial and general public. The former are held either in a particular company or organisations premises and are specifically for the employees of that organisation, or in a location which employees from several companies can visit or be transported to. For those RTCs with a "blood-mobile" - a mobile collection vehicle - a further option is available. These have proved useful for small industrial sessions, particularly for the new type of light industrial estates where no one firm has enough employees or accommodation to merit a session, but the estate in total can provide sufficient donors. The blood-mobile can also be used for smaller general public sessions where a hall is not available.

3.7 The industrial recession has reduced the number of firms available for industrial sessions. In Mersey region 80% of sessions were industrial in 1976 but this has now dropped to 35%. Firms have closed or reduced their workforce below the level that makes a session viable. Nationally industrial sessions represent about 28% of all donor sessions and provide about 25% of all usable donations. The proportional split of sessions covers a wide range eg in one region in the north industrial/commercial sessions represent 6% of all sessions whilst in another region in the South they represent 48%. Table 3 (page 148) shows the number of industrial and general public sessions held in each region. The RTC with the low rate recognised the potential damage to its donor base from the recession and moved to a deliberate policy of general public sessions. In some regions the decline was unforeseen and has required hard work on the part of RDOs to make up the loss. In other regions where

commmerce and light industry is increasing it is still possible to mount a significant number of sessions although some companies are no longer prepared to bear the cost of allowing donation in their time. Obviously such factors have differing significance in individual regions but from a long term strategic viewpoint the balance between industrial/commercial and general public sessions is an issue that the BTS should consider.

3.8 Sessions are generally of 4 hours duration split into two, two hour bleeding periods. They are either morning and afternoon (early) or afternoon and evening (late). Typical times for an early session would be 10-12 am and 2-4 pm. For a late session times might be 2-4 pm and 5-7 pm. Industrial sessions are usually early and those for the general public late. RDOs have been under pressure to put on more morning sessions to increase the availability of fresh blood for platelet production. This has proved difficult against a background of declining industrial sessions. It has led to some Regions experimenting with more early general public sessions. These have received a mixed reception from the donors. The most popular times for donating by the general public appears to be firstly the early evening, secondly the afternoon with morning sessions generally a poor third.

3.9 The use of weekends for bleeding varies and some RTCs tend to limit such sessions because of the extra cost involved. Where weekends are used centres generally prefer Sundays so as to provide a head of work for the laboratories on Monday mornings without which they would have no blood to process or test. Several regions suggested that donor response is often good at Sunday sessions.

3.10 Once an outline plan has been arranged halls are booked and factories notified of when sessions will be held. Where dates prove inconvenient rearrangements have to be made. RDOs usually like to issue a firm programme 6-8 weeks in advance of the session.

Session Call-up

3.11 Call up of donors is 2-3 weeks in advance of the session. Some RTCs have fully computerised their donor call up, in others the process is semi-computerised or wholly manual. In general call up is handled from the RTC but some centres also have local volunteer organisers who may be involved in the process. Each donor has an individual record, with a unique donor

number, which contains a range of relevant information such as blood group, details of all donations given etc. The records are stored by panel - a panel comprises all donors that attend a particular session or session location.

3.12 To call up a panel it is necessary first to identify those donors who are due and able to be bled from: those donors who gave last time; those donors who failed to attend last time; new donors not yet bled; and donors who were deferred last time due to, for example, pregnancy or illness. The aim of the call up is to produce a certain number of donors. To call too few will result in an under employed session, too many can lead to long waiting times and disgruntled donors. The targets vary between regions, some aim for 100 per session others for 140, as do the response rates which range from 30% to 60%. Table 4 (page 149) shows the response rate per region. The response rate at general public sessions ie, the proportion of those called that actually attend, does not appear to be related to session targets and is in most regions remarkably constant year on year. Some RDOs have suggested that it is a characteristic of a particular regional population, others dispute this. We have been unable to determine any particular explanation for the variation.

3.13 Donor records require to be updated and changes may be notified either in writing or reported at donor sessions. The detailed donor record procedures vary between regions but in essence the systems are the same whether manual or computerised. Obviously the manual systems are extremely staff intensive. Of two similarly sized RTCs the computerised donor records department employed six staff whereas the manual system employed eleven.

3.14 Donors are not normally selected for sessions by blood group. It is assumed that the required groups will attend in broadly the proportion in which they exist in the population. One RTC with a computerised system has however recently started to weight sessions away from A Rhesus positive donors in an effort to reduce a surplus of blood which cannot be used or exported to other regions. Other computerised centres have given their donors reliability ratings which enable more accurate predictions of attendance to be made.

3.15 Donor records should be transferred between regions when a donor moves but there are indications that this system is not fully effective. Additionally some regions weed their panels more regularly than others to remove donors who have failed to attend a particular number of sessions etc. As this number also varies between regions it is difficult to assess the system but this may be a factor that affects the response rate.

Donor Recruitment

3.16 RDOs are responsible for the recruitment of donors; the promotion of the BTS and the advertising of sessions. Publicity budgets vary according to the difficulty of recruiting and retaining donors within the Region. RDOs build up relationships with local media and can obtain much free publicity in this way. There is a national committee for publicity chaired by an officer of the DHSS. This has a budget of £350,000 for 1986/87 for nationally produced publicity material.

3.17 Donors are recruited in a variety of ways such as advertising, personal contact or via existing donors. Publicity trailers are used for agricultural shows etc and prospective donors complete a simple enrolment form from which they will be called on the next convenient occasion. In general it is found that the longer the period between the donor being enrolled and called, the less likely it is that they will attend. Some RDOs have a rolling recruitment campaign planned up to 5 years in advance. Large population centres are the subject of a campaign on a regular basis to boost the panels. Sessions are arranged to follow close on the recruitment drive in order to maximise the conversion of enrolled donors into actual givers of blood. Other RDOs organise specific campaigns for panels which are declining. Most centres have used the "bring a friend" approach with varying success.

3.18 Turnover of donors varies from 7% to 20% and it is highest in those centres with large urban populations. This means that some centres need to recruit up to a fifth of their donor panel each year merely to stand still. Not all regions were able to supply the relevant figures but from those obtained it would appear that, over England and Wales as a whole, the total number of donors increased slightly between 1984 and 1985. Table 5 (page 150) shows the pattern of donor recruitment and losses across the regions.

3.19 RDOs have regular meetings to discuss common problems and exchange ideas. In addition divisional meetings are organised and, as previously mentioned there is a national publicity committee. Through these various meetings the RDOs endeavour to co-ordinate their activity to some extent. Nevertheless, publicity over spill from one region to another can occur and produce difficulties from time to time. Most commonly this will be when a London Region makes an appeal for blood. Donors commuting into London from the Home Counties are influenced by this publicity but turn up at donor

sessions in their Regions rather than the Region that is short of blood. Needless to say, the name "National BTS" gives the impression to the public that if blood is needed in one place, they can give it at another and the BTS will get it to where it is required. There is no formal arrangement to make this happen. There is little evidence of consideration of issues in which for example one region's experience maybe a sympton of a deeper problem which has implication for the whole service eg the impact of the recession on collection patterns.

3.20 On a number of occasions during the study the recruitment of donors was likened to a marketing operation and there are similarities. In the light of this we were surprised that relatively little research has been done on donor motivation or preferences.

3.21 Similarly the amount of systematic session performance information collected is minimal. Typically a session report sheet is completed for each session which details the number of donors attending, rejected (with reasons), full packs obtained, plus comments on the hall and arrangements generally. These documents are filed under the panel name and may form the basis of panel reviews to determine whether recruitment is required to boost the panel etc. However, there is not much evidence that systematic databases are maintained from which, for example, early warnings of donor drop off might be extracted. This is not entirely surprising since keeping these records manually can be a labour intensive task. Here again computerisation can be of significant help. One RTC where the donor records are fully computerized is beginning to build up a database which analyses donors by sex and age; team performance; collection rates by district health authority, etc. This will provide the potential for a more sophisticated approach to session planning and allow greater manipulation of the existing donor base. It would in their view, have been virtually impossible to collect this information under the previous manual system.

4. BLOOD COLLECTION

Synopsis

There are considerable operational and policy differences in the collection of blood in the 14 Regions. We accept that there are some physical factors that will dictate the level of overall resources that an RTC has to devote to blood collection eg the distance of the RTC from its collection centres. However we conclude that the wide variation in, for example, the number of donors processed per session per team member cannot wholly be attributed to such factors and that the blood collection operation in RTCs offers scope for some rationalisation.

4.1 Every region collects blood by deploying mobile teams in its catchment area to bleed volunteer donors. In addition every centre except one has some bleeding facilities on site, either for whole blood collection, plasmapheresis or both. Eight regions have one or more permanent city centre donor suites which usually collect both plasma and whole blood donations. Four regions employ Bloodmobiles: vehicles adapted for whole blood collection where accommodation is not available.

Tasks

4.2 The tasks that have to be carried out in the setting up, running and taking down of a blood donor session are broadly similar throughout the regions. They are:-

4.2.1 transport of teams and equipment from RTC to session and back;

4.2.2 setting up session;

4.2.3 clerking in donors and the completion of paperwork connected with the blood donation;

4.2.4 testing each donors haemoglobin level to ensure he/she is fit to donate;

4.2.5 assessment of donors medical fitness to donate;

4.2.6 venepuncture including sterilization and anaesthetising of site of insertion of needle;

4.2.7 care of donor during and after donation including provision of refreshment;

4.2.8 disconnection of donor from bleed line, labelling donations etc;

4.2.9 packing of donations for transport back to the RTC;

4.2.10 taking down of session.

In addition to the above, two regions group the blood from donors at the session at the same time that the donors' haemoglobin is tested.

Aspects of Performance

4.3 The number of staff employed to perform the above duties, their titles and role within the team vary from region to region. Table 6 (page 157) gives the composition of mobile teams for each region. The figures quoted are the norm for each region or the range if the size of team is varied according to the number of donors expected or other circumstances. Teams may go out with more or less donor attendants (DAs) dependent on leave, sickness etc. Also shown are the average number of donors attending each session and the number of donors dealt with per team member per session.

4.4 Whilst there is some variation in the length of a session from region to region this does not significantly affect the conclusions to be drawn from Table 6. Broadly speaking the larger the team, the more donations that it can collect. However there are some significant variations to this rule. Region A run some of the largest teams yet have the smallest throughput of donors per session. Regions E and G use the same size teams yet G deals with 32 more donors per session on average; similarly Regions C and A use 15 team members per session yet C can process 51 more donors per session on average. Region M questions whether a session is viable if the numbers attending drop below 140 per session: Region A consider spreading the session over 2 days if the numbers reach that level.

4.5 No formal analysis of the procedures operated at donor sessions was undertaken but discussion with the staff involved and observation of some sessions revealed marked differences in the way in which the duties outlined at para 4.2 are performed and who performs them. For example:

4.5.1 as can be seen from the Table in some regions the drivers are expected to perform tasks during the donor session. In others they have no duties except, when necessary, transporting donors to and from the session. Those centres where drivers have no other duties accept that

this is generally an under-utilization of the drivers. This has been mitigated to some extent in recent times by the fact that blood often needs to be returned to the RTC during the session for the production of platelets and some regions, but not all, use the session drivers for this purpose;

4.5.2 some Regions use drivers as clerks or haemoglobinists. The difference between regions in what is expected of drivers (virtually all of whom are ASC grade 6), can be a cause of some industrial discontent. The BTS driver gradings do in fact allow for them to perform clerical or technical duties but some regions choose not to take advantage of this provision, sometimes apparently because of problems in recruiting drivers of an adequate calibre to do the additional duties for the remuneration available;

4.5.3 there are variations in the performance of the haemoglobin test and who does it. In some regions drivers do it; in others DAs do it; in yet others it is done by a JMLSO (see page 25). Whilst most regions obtain the blood sample from the forefinger or thumb one RTC obtains the sample from an ear lobe. As mentioned previously two regions also use the blood sample to do an initial group on the donor. All regions use a copper sulphate solution to test the donors for anaemia. In some regions a haemoglobinometer is used to test those who fail this test. It is argued by its proponents that this allows more donors to be bled and gives the donor an immediate and accurate assessment of whether they are anaemic rather than having to wait for a laboratory test result. In regions where a haemoglobinometer is not used (and in some where it is) a sample is taken by the MO for a laboratory test for anaemia;

4.5.4 where the clerking is not performed by a driver it is done by a clerk who is normally on the establishment of the RDOs department. In one or two Regions a recent development has been the training of DAs to undertake clerking duties. This introduces an element of flexibility into the session, enabling the regular clerk to be given assistance during peak times of donor arrival. The majority of Regions manage with one clerk per session but six use two. It is notable that the Region with the smallest throughput of donors per team member per session uses

two clerks while that with the highest throughput manages with one. The use of two clerks appears to be useful in reducing waiting time when a large number of donors arrive together but overall does not seem to be crucial in achieving a high throughput;

4.5.5 the actual equipment used on session (and indeed the vehicles) varies, particularly the beds. We have heard convincing arguments for solid, metal framed beds and light plastic ones. To the layman it is seems reasonable to suppose that a "universal bleeding bed" could be developed thus achieving standardisation and the potential for volume discount for bed purchase. It would also remove the need for each RTC to evaluate a range of beds when they need to replace their stock. At least one RTC has designed a bed and had it manufactured.

Pre-Donation Screening

4.6 Screening donors for medical fitness to donate is usually a two stage process. Normally the clerk or haemoglobinist asks the donor basic questions on the taking of medication, visits abroad etc and can refuse donors who are clearly not eligible to donate. Doubtful cases are referred to the MO who makes the final decision. A further check is generally provided by the DA who prepares the donor for bleeding who will attempt through conversation to identify any reason why the donor should not donate.

4.7 In all regions except North East Thames an MO is present at blood donor sessions. His or her job is to be the final arbiter of whether a donor is fit to donate; to perform the venepuncture; and to make medical decisions in relation to donors who react badly to donating or have an accident afterwards. In regions where there are qualified nursing staff present at sessions they may venepuncture under the supervision of a MO though this is most often the case at RTC static bleeding sites.

4.8 North East Thames (NET) are phasing out the use of MOs at donor sessions and replacing them with qualified nurses. These are recruited as SRN Staff Nurses and promoted to Sister on successful completion of a six month training course. Nurses were introduced into sessions because of difficulties in recruiting MOs. Initially it was thought that the system would also be

cheaper. The long training period, and a proposal to have two sisters per session suggests that the projected savings may not be achieved. However some doubt has been expressed elsewhere about the necessity for such a lengthy period of training and the second sister.

4.9 NET have demonstrated the viability of using nurses to run sessions, and suggest that there are additional spin-off advantages such as consistency of decisions as to who to bleed and better team harmony. Some regions are favourably disposed to the system particularly where the recruitment of MOs and/or consistency in judgements is a problem. Others, probably the majority, however are set against it primarily on the grounds that it may cause unease among donors or would reduce the effectiveness of the medical response if an accident occurred.

4.10 Guidance on the criteria for the selection of donors is provided in a booklet drawn up by the RTDs. It leaves room for quite a lot of interpretation. This is compounded by the part time nature of the employment of many sessional doctors with the result that it is not always possible to achieve a consistent approach between, and some times within, regions. The number of donors "turned away" at a session as a percentage of those attending varies between 5% and 16%. Figures for each region are given in Table 4 (page 149). The underlying causes of this variation are difficult to detect. Clearly they are a function of:

4.10.1 refusal/deferral policy;

4.10.2 health of catchment population;

4.10.3 testing regime of the RTC;

4.10.4 propensity of catchment population for "high-risk" activity such as foreign travel, drug abuse, tattooing etc;

4.10.5 the difficulty of attracting donors to sessions and the demand for blood.

It would need a detailed investigation of each RTC to disentangle these factors. However it might be useful for RTCs with a high rejection rate to compare their bleeding criteria etc with those with a low rejection rate, particularly as the potential for increased donations if each centre achieved the rate of the best is about 60,000 per year.

Donation

4.11 Donor attendants look after the donor whilst he/she is bleeding. In eight centres one DA looks after one donor during bleeding; in six there is one DA for two bleeding donors; and in one a pool of five or six DAs jointly look after all the donors who are being bled. Again, there does not appear to be any correlation between efficiency and the number of donors a DA looks after.

4.12 The DA who looks after the donor during bleeding will take down the giving set once 450 mls of blood have obtained. One or two centres bleed lesser amounts from certain classes of donors, generally for laboratory use. There are machines available which ensure that donors are not overbled and their use might avoid the necessity for donors to be constantly monitored by DAs. We did not see such equipment in operation and some people expressed the view that donors would not welcome it's use. We are not aware that the machines have been trialled or objectively evaluated within the BTS. Once the donor is disconnected from the blood pack it has to be labelled (in those centres where packs are labelled at session), and the bleedline stripped ie the blood in the bleed line is pushed into the main pack to ensure throrough mixing with the anti-coagulant. This line may also be sectioned as it will be the source of samples for cross matching etc in hospitals. The full pack has also to be taken to the point at the session where the blood is collected together, and sometimes sorted into groups, for return to the RTC. These tasks may be undertaken by the DA that bleeds the donor; by a DA specially designated to do them; by a driver; by the Team leader; or a combination of these.

4.13 At the end of the bleed the DA also fills two sample tubes with blood and labels them. These will be used for grouping and virology tests at the RTC.

Post Donation

4.14 Following donation the donor is rested for a period. This may be on the same bed on which they were bled or it may be on a different bed. In one region donors are not rested on a bed unless they feel unwell. Resting periods vary from 10-20 minutes after which the donor is served with a drink

and leaves. Resting is usually supervised by at least one DA. Volunteers, when available, may assist with teas, resting area and, in one or two regions bandaging of the puncture wound. We were surprised at the extent of voluntary help used. Most regions had volunteers (normally one or two individuals) at some or all sessions. RTCs were of the opinion that additional staff would need to be employed if this help was not available.

Team Management

4.15 The MO is usually nominally in charge of the collection team but in practice the Team Leader is in operational command. Team leaders are usually DAs who have risen through the ranks although one region has a positive policy of gradually replacing DA team leaders with SENs.

4.16 Whilst all staff (except the MO) are expected to carry out the Team Leader's instructions on sessions, in most regions there will be staff on the collection team who have no line management responsibility to the Team Leaders. For example, drivers are usually responsible to the Transport Officer; JMLSOs where deployed, are responsible to the head of laboratories; and clerks are normally responsible to the RDO. These different lines of responsibility can complicate the Team Leaders position. One region has sought to avoid this by appointing a Team Manager. This individual has line management responsibility for all the collection team staff.

4.17 In 6 of the 14 regions some sessions require the collection teams to stay away overnight. It is recognised that these donations are relatively expensive although cost is not the only criteria here and the quality of donations also needs to be taken into account. Often these sessions, being held in rural areas, are well attended but calculation of the cost benefit relationship is rarely made. Some regions have outstationed one or more of their teams in an efforts to cut down, or eliminate, "stay aways" and travelling time in general. There is a widely held view within the BTS that if a session is viable in terms of the number of donations obtained then it should be held, to an extent regardless of cost and whether an equivalent number of donations could be achieved elsewhere at less expense. This is in order to preserve what is regarded by many in the BTS as the right of the donor to donate his or her blood.

4.18 An almost universal problem that Regions are at present confronting is the payment of day subsistence. It appears that the Whitley rules are sufficiently ambiguous to allow a range of interpretations of when it is payable and whether at the higher or lower rate. In many Regions payment of these allowances is based on theoretical times of return to the RTC and these have often not been updated to take account of road improvements which have reduced journey times. Variations in practice between regions can be a focus for industrial unrest but the BTS does not appear to be attempting to produce a co-ordinated approach to the resolution of the problem.

4.19 Close co-ordination is required between the RDOs department and the laboratories for the effective deployment of collection teams. The relationship between these departments varies from RTC to RTC. In some the RDO department takes precedence and the teams and laboratories have to plan their work around the programme arranged by the RDO. In others the laboratories take precedence and the RDO is required to produce sessions for their convenience. In yet others, restrictive working practices by the teams dictate the RDOs programme and laboratory arrangements. As with many of the RTCs activities lack of management information inhibits the ability of those responsible for the deployment of the collection teams to evaluate and monitor performance and thus to use them to their maximum potential.

5. SCIENTIFIC AND TECHNICAL SERVICES

Synopsis

We have found that there is no complementing system to determine how many staff are required for particular volumes of scientific or technical work. In addition there are differences between RTCs as to what work is appropriate to PTA and PTB grades. Similarly there are different approaches to the use of ancillary staff in laboratory areas. These differences appear to be reflected in the cost effectiveness of different RTCs though this is difficult to substantiate due to the general lack of management information and the fact that in most RTCs different laboratories, or areas of scientific and technical work, do not have their own budgets. The range of different techniques used in the RTCs to perform similar tasks results in different laboratory organisations and efficiency. There is no formal system for diseminating good practice and in particular the question of common quality assurance/control practices has only recently begun to be addressed.

Introduction

5.1 A large proportion of RTC resources are devoted to the scientific and technical tasks of testing, grouping and processing the blood collected. In addition there are other tasks of a diagnostic nature which some RTCS undertake. All of this scientific/technical work needs to be supported both by qualified and ancillary laboratory staff. In consequence these staff form the largest group of staff within RTCS, (about 35% see Table 2 page 147).

5.2 Within an RTC the scientific and technical work is divided up between laboratories. Whilst there is no standard division of tasks between laboratories the main tasks are reasonably uniformly distributed. The main laboratories and their tasks are briefly detailed below:

5.2.1 grouping laboratory - ABO and Rhesus grouping of donations. May include antibody identification and reference serology on difficult groups for hospitals;

5.2.2 transfusion Microbiology - testing donations for Hepatitis B, HIV and syphilis plus other microbiological tests;

5.2.3 blood products - processing of whole blood into its component parts eg. plasma, red cells, platelets etc;

5.2.4 blood bank - the storage and issue of blood and blood products;

5.2.5 research and development;

The above are carried out at all RTCs. The following tasks are carried out to varying extents:

5.2.6 reagent production - production of diagnostic reagents from human, animal and plant sources. May also include preparation of crystalloid solutions;

5.2.7 ante-natal testing - diagnostic tests on blood samples taken from pregnant women;

5.2.8 tissue typing - matching organ and bone marrow donors with patients and the identification of diagnostic reagents for tissue typing. May also include a diagnostic disease association service.

Staffing

5.3 Staff involved in laboratory work belong to either the Medical Laboratory Scientific Officer (MLSO) or the Scientific Officer (SO) grades (PTB and PTA groups). In addition there are laboratory ancillary grades for some tasks. The MLSO staff hierachy is as follows:

5.3.1 Junior MLSO (JMLSO) - entry training grade;

5.3.2 MLSO - basic qualified working grade;

5.3.3 Senior MLSO (SMLSO) - 2nd level working grade. Before qualifying to apply for a SMLSO post an MLSO has to pass exams qualifying him/her to be a Fellow of the Institute of Medical Laboratory Sciences (IMLS);

5.3.4 Chief MLSO (CMLSO) - first level management post. Often in charge of a laboratory, but still likely to be involved in "bench work";

5.3.5 Senior Chief MLSO (SCMLSO) - second level managerial grade. Usually in charge of a group of laboratories: may be head of RTC laboratories in some transfusion centres. Little bench work involvement;

5.3.6 Principal MLSO (PMLSO) - third level managerial grade. Head of RTC laboratories in some RTCS. The post is virtually all managerial work.

The appointment of the top three grades is to some extent dependent on the number of lower grades supervised although the quality of the work undertaken can also be taken into account. In the appointment of a PMLSO however there appears to be fairly strict adherence to the criteria that 63 MLSO staff (all grades) must be employed. Staff in the MLSO structure represent about 60% of all Scientific and Technical staff in RTCs (including ancillary staff employed in laboratory areas).

5.4 The scientific officer scale has four grades: Scientific Officer (SO); Senior Scientific Officer (SSO); Principal Scientific Officer (PSO); and Top Grade Scientific Officer (TGSO). These staff may also be employed in either managerial or bench work posts although the majority are involved in bench work.

5.5 Entry to the SO grade requires a degree whereas entry to the JMLSO grade can be made with O level qualifications. Staff appointed as JMLSOs normally undertake a programme of training which, if they are successful, qualifies them for MLSO status. Entrants to the SO grade are not expected to undertake any further formal training although many do study for higher degrees. JMLSOs are required to attend day release courses etc hence the amount of "productive" time available to the BTS is limited. This can distort the picture when comparing number of staff on the establishment.

5.6 Slightly more than 900 qualified staff (ie. excluding ancillary grades) are employed in BTS laboratories of which just less than 10% are SO grades. In most centres the majority of laboratory staff are MLSO grades but the ratio of SO group staff to MLSO group staff varies enormously from 1:5 to 1:68. In one centre there are more SO grades than MLSO grades and two centres have no SO grades at all.

5.7 Line management can be a problem with this mix of staff grades. In theory MLSO staff only report to MLSOs and SO staff to SOs. In practice, laboratory management in many centres results in SO grades being responsible to MLSOs or vice versa. Indeed, in one RTC the overall manager of the laboratories is a TGSO. From a practical perspective it is certainly not clear in many cases why there should be two separate staffing structures. We have found jobs done by SOs in one centre and MLSOs in another. Quite a lot of the scientific staff we spoke to questioned the need for separate structures. Since an increasing proportion of MLSO staff now have first degrees there is no longer necessarily a difference in qualifications between them and SO grade staff. If ever there was a time when there was a clear distinction between work appropriate for MLSO staff and that appropriate for SO staff that distinction is now very blurred in the BTS.

5.8 In some centres particular medical staff are identified as being associated with or responsible for a laboratory or group of laboratories. There is generally no direct line management accountability however and the staff working in the laboratories regard themselves as being responsible via the head scientist to the RTD. In practical terms the association appears to involve maintaining a medical overview and providing a source of medical advice. Medical staff may also have clinical interests or research projects which lead them to take a close interest in particular laboratories.

5.9 Apart from qualified staff the laboratories also employ ancillary staff, variously described as laboratory assistants or aides, blood bank orderlies, animal house attendants etc. The following list is not exhaustive but provides an indication of the types of task which are undertaken by ancillary staff:

5.9.1 the simpler tasks associated with the processing of blood eg. plasma pressing;

5.9.2 washing of re useable glassware and equipment;

5.9.3 autoclaving;

5.9.4 storage of blood and making up of orders for issue to hospitals;

5.9.5 looking after laboratory animals.

5.10 The line of demarcation between some aspects of JMLSO and ancillary staff work is blurred. In some RTCs ancillary staff are used for plasma pressing, in others JMLSOs do this work. Most laboratory managers agreed that many of the production processes carried out in blood products laboratories could be done by semi-skilled staff under the supervision of MLSOs. However there does not appear to be a suitable grade to recruit to. One or two centres have resorted to employing staff at JMLSO wage rates but (with their agreement) not training them. It must also be remembered that it is against the interests of an MLSO laboratory manager to downgrade work from JMLSO level since his own grading is dependent on the number of MLSO staff employed.

5.11 We have found considerable variations in the number of laboratory staff employed in RTCs, both overall (allowing for the differences in workload) and between broadly comparable tasks. The different methods of dealing with similar tasks make direct comparison difficult. In the description of laboratory work in the following sections some examples are given of instances of different levels of staffing. The basic problem is that there is currently no complementing system for scientific staff ie. no uniform way of matching numbers and grade of staff to the volume and type of work to be undertaken. Currently staffing levels are broadly determined on historical grounds.

5.12 It should be possible to produce a complementing system for scientific staff but it would be a complex task. Some work has been done on forms of workload measurement in two or three RTCs. The lack of systematic and uniform management information systems in the laboratories is, as elsewhere in RTCs, a handicap to performance evaluation. Whether or not it proves possible to develop complementing indicators the management information system recommended in chapter 9 should enable comparisons to be made and hence the development of a more objective approach to staffing requirements.

5.13 Overall then the present scientific staffing arrangements are not entirely satifactory. The changing nature of the scientific and technical task in RTCs has not led to corresponding changes in the staff structure. The scientific management arrangements and grades of staff employed on comparable duties also vary from RTC to RTC. It has been suggested that a single grading structure for scientific staff within the BTS, including ancillary staff, could help resolve these problems. Whilst the solution has its attractions it has to be remembered that BTS scientific staff form only a small proportion of

the total scientific and technical staff employed in the health service. To develop a separate staffing structure for the BTS could isolate its staff from the rest of the NHS laboratory service and lead to a diminution of career prospects. It is also unlikely that the Management Side of the relevant Whitley Council would be keen to negotiate separate terms and conditions of service for so small a group of staff although this could depend on organisational considerations. Streamlining of the scientific and technical staffing structure within the BTS may have to await a more general move for such a change throughout the NHS scientific community.

5.14 In the following sections we describe in general terms the arrangements we have found for carrying out the main laboratory tasks undertaken in RTCs. Some functions are organised in much the same way throughout the BTS eg every RTC has a discrete blood products laboratory. The combination of other laboratory functions differs widely as do the titles given to the various laboratories undertaking them for example in one centre the Grouping laboratory deals with all blood grouping but also provides the Special Reference service (often a separate laboratory in other centres) and produces Reagents (also often a separate laboratory). In another centre the Ante Natal laboratory also produces reagents and the "grouping" function is split between two other laboratories and combined with other functions. It has therefore proved extremely difficult to isolate individual functions and the resources devoted to them. In the succeeding paragraphs therefore we do not list laboratories and describe their functions but rather describe function under generic headings such as Serology etc and attempt to indicate the ways in which the main aspects of the generic function are organised and carried out. We have not attempted to describe all laboratory practices in detail.

Serology

5.15 The main serological tasks carried out by RTCs are as follows:

5.15.1 ABO and Rhesus blood grouping of donors;

5.15.2 genotyping of donors;

5.15.3 ante-natal blood tests;

5.15.4 antibody identification and quantitation on donor and patient blood;

5.15.5 blood group reference work including difficult cross-matches and transfusion reactions;

5.15.6 blood grouping reagent production;

5.15.7 routine crossmatching.

5.16 Although the division of these tasks between separate laboratories is different in virtually every RTC most of them, except ante-natal testing and routine crossmatching, are carried out in all RTCs to some extent. In the following paragraphs we do not discuss each of the major aspects only those which, in our view, are relevant to consideration of the current and future organisation of the BTS.

Blood Grouping

5.17 The ABO and Rhesus blood groups of each donor (and hence each donation) are determined every time he or she donates. To this end two samples of blood are taken from each donor at the time of donation. Each sample is labelled with the same unique number and bar-code as the blood bag containing the donation. This is to enable the grouping result to be associated with the donation when testing is complete.

5.18 All donations are grouped at least once, those of new donors (ie donors for which the RTC has no records) twice. Known donor's grouping results are checked against previous records of that donor's blood group. New donors, having been tested twice, have the two results checked against each other. Blood is only cleared for issue when the two results tally.

5.19 All RTCs use blood grouping machines to group the donor samples. There are three types of machine in use: two made by Kontron - the G2000 and the 360, and one made by Technicon - the AG 16C. The number of machines in RTCs varies from one to three dependent on how many donations they have to group per day and whether the machines are used for ante-natal work as well. Eight regions use Technicon machines, the other six Kontron.

5.20 In general RTCs group blood the morning of the day after it has been collected but they are increasingly having to process and issue some blood on the same day as it is collected. In these circumstances blood from a morning session will be grouped the same afternoon. Blood samples are batch processed. Simplistically both types of machine take the sample and mix it with a number of different reagents. After allowing time for any reaction to take place the results are read automatically and stored on floppy disc/printed out by donation number. The difference in the machines is the number of "channels" they have which determines the number of tests that can be performed on a sample as it passes through the machine. The Technicon has 16 channels allowing the sample to be mixed with up to 16 reagents. The Kontron G 2000 operates in either a 9 or 18 channel mode and the 360 has 12 channels.

5.21 The check test for new donors may be performed in a number of different ways. Two RTCs actually do a manual rapid "tile" group at the donor session. This is done at the same time as the haemoglobin test (see paragraph 4.2). The rest do the check test in the laboratory. It is either done manually or automatically, the samples being put through the machine again with a different configuration of reagents.

5.22 We attempted to establish why these procedure should differ between RTCs but without much success. The proponents of manual testing argue that it is more reliable and enables staff to "keep their hand in" in the event of machine breakdown. These who favour automated testing argue that it is more reliable than manual testing and that there are staff available in the RTC who use manual techniques on tasks where automation is not suitable and would thus be available to assist in the event of machine breakdown. Manual testing is more staff intensive but as we indicate at paragraph 5.26 valid comparison is difficult became of the absence of reliable benchmarks. By way of illustration one centre groups 20,000 more donations and handles routine ante natal tests with 7 fewer staff in the grouping laboratory than another centre which does not do routine ante natal testing. The first centre does the check test on the machine the second does it manually.

5.23 All the machines fail to group a certain percentage of samples on the first run. Generally these are put through again but a number (variously quoted as between 2%-5%) will remain that the machine cannot group. These, plus any others samples that cannot be put through the machine, are done

manually. Manual testing may be carried out in the same laboratory as the automatic grouping or in another which is dealing with samples from other sources that require manual grouping. Most centres have at least two machines so that if one breaks down there remains some capacity for automatic grouping. One or two centres with only one machine have to resort to manual grouping if the machine breaks down.

5.24 Once the grouping results have been obtained they have to be associated with their corresponding donation, and in the case of new donors, with the donor record card. This may be done manually or by computer. Manual systems are necessarily labour intensive and the RTCs that have yet to computorize expect to do so in the near future. Most commonly the results are recorded on a floppy disc by the microcomputer that controls the grouper. These can then be edited by the laboratory staff. The disc is then transferred to another microcomputer, usually near the blood store, on to which the donations have been logged. The two databases are combined and then the blood packs labelled and verified using light pens and the bar-codes. Where all donor and laboratory information is held on one database the grouping machine feeds the grouping results directly to the database and they are automatically checked and correllated with the donation.

5.25 It is difficult to make comparisons of performance between regions because the mixture of tasks undertaken by different laboratories in each centre make it virtually impossible to isolate one activity in resource terms. The breakdown provided by the Cost Form 60 is given in Table 7 (page 152), but as can be seen this is only loosely related to individual laboratory costs. For example the grouping laboratory may deal with one or any combination of the following: automated grouping, manual grouping, ante-natal testing, blood banking and reference work. The costing information derived from RTC accounts gives a range of grouping costs per donation of £1.13 to £3.67 with a mean of £2.49 (see Table 8 page 153). Although we cannot be sure that all RTCs have attributed the same costs to grouping if these figures represent the true situation then, in money terms, the cheapest RTC is three times as efficient as the most expensive.

5.26 The limited number of suppliers of grouping machines means that each machines characteristics are well know in the RTCs. There are user groups for

the machines where problems and ideas are discussed. When machines have to be replaced it is up to the individual RTC to decide which machine to buy - there is no central buying policy. Nor is there any central contract for maintenance.

5.27 The recent major technological innovation in blood grouping is the use of microplate techniques and the development of an automatic grouping machine using microplate technology. One such machine has been evaluated at Birmingham RTC and copies of the evaluation will be available to all RTCs. Such an approach could perhaps be developed into a "best buy" policy which might be of advantage to the BTS.

Ante-natal Testing

5.28 This service is provided to identify pregnant women with irregular antibodies that may either cause haemolytic disease of the newborn or present difficulties if a blood transfusion is required during or after birth. The tests are carried out either in hospital laboratories or at the RTC.

5.29 The basic test involves grouping the mothers blood on the ABO and Rhesus systems and screening it for the presence of antibodies. If antibodies are found further tests are carried out to identify them and quantitate their volume in the blood. Blood samples from the mother are generally tested at least twice during pregnancy: if irregular anti-bodies are identified testing may be more frequent, up to fortnightly in some cases. RTCs also test the samples for syphilis.

5.30 All RTCs provide an ante-natal reference service for the whole region. Some RTCs also provide a routine ante-natal testing service, ie they group and screen all samples for antibodies and carry out any other tests that are necessary. Five RTCs provide this service to the whole of their region and a further six RTCs offer it to part of their region. Hospitals that carry out the routine test (group and screen for antibodies) may refer the sample on to the RTC to identify and quantitate the antibodies. Hospitals may do their own identification and quantitation but will still find some samples they cannot resolve and these they send to the RTC for investigation (the reference service).

5.31 Whether the routine testing service is provided at the RTC or in hospital, and if at the RTC the extent of that service, seems to be often a matter of historical accident. We are not aware of any region that has done a cost benefit analysis to determine the location of the service. Ante-natal testing is an area where the past or present RTDs interest (or lack of it) or the interests of other doctors in the region can have a bearing on where the service is provided and how it develops.

5.32 The proponents of routine ante-natal testing being carried out at RTCs argue that:-

5.32.1 economies of scale can be achieved by large volume testing;

5.32.2 the RTC is the respository of expertise on serology and techniques for testing large numbers of samples;

5.32.3 there is ready availability of diagnostic reagents;

5.32.4 it enables RTCs to identify women with antibodies (especially Anti-D) that will be useful for the production either of immunoglobulins or reagents, particularly tissue-typing reagents. These women can be approached after birth with a view to recruiting them as specific plasma donors;

5.32.5 ante-natal testing extends the range of work available to RTC scientific staff. This helps to sustain interest in the job as well as presenting training opportunities;

5.32.6 testing is uniform and to consistent standards;

5.32.7 although blood samples have to be transported to the RTC this is generally done by the vans on blood delivery rounds and therefore does not actual "cost" anything.

5.33 The counter arguments are:

5.33.1 The availability of small scale autogroupers and autoanalysers means that the economies of scale may not be as large as claimed;

5.33.2 doing the tests at RTCs can lead to delays in the hospital/clinician getting the results. The critical task for an RTC is to collect and distribute blood and blood products. If for example staff shortages require the RTC to prioritize it's work, then ante-natal tests may be delayed for a time as they are in general relatively non-urgent;

5.33.3 the advantage for the RTC quoted at 5.32.5 above is a disadvantage for the hospital - it's staff lose an area of expertise and interest which makes their job less attractive.

5.34 It is beyond our remit to comment on the most economic and efficient site for routine ante-natal testing, to do so would require a detailed examination of the relative costs etc of RTCs and hospitals. However the location of such testing does impact on consideration of the future organisational and funding options for the BTS. If it were decided to centrally fund the BTS without deciding on the location of this work, such funding would have to cover the varying levels of service currently provided. Alternatively no funding might be provided for antenatal work and the BTS and RHAs required to jointly resolve the financing arrangements. In the longer term the latter arrangement could lead to an objective consideration of the question of location.

5.35 Where an RTC provides only a reference service the work is often combined with other serology reference work in one laboratory. The resources devoted to ante-natal work vary between RTCs and depend to an extent on the scale of the service provided. For example one RTC provides a routine service to approximately half the region with 10 staff; another provides a routine service to the whole region, dealing with about 3 times as many samples, but also uses 10 staff. Additionally since each test has to be documented and records kept for ten years clerical resources are also required. We estimate that nationally at least 90 staff are involved in ante-natal work in the BTS.

Serological Reference Service

5.36 All RTCs provide a reference service to resolve serological problems which hospitals cannot deal with. The sort of problems that may be referred to the RTC include:-

5.36.1 crossmatch difficulties;

5.36.2 blood grouping problems

5.36.3 identification of, or confirmation of, antibodies detected by a hospital prior to transfusion;

5.36.4 quantitation of antibodies;

5.36.5 investigation of transfusion reactions; and

5.36.6 investigation of suspected Auto-Immune Haemolytic Anaemias.

The RTC will attempt to resolve any serological problem for hospitals. Anything that the RTC cannot resolve is passed on to BGRL (the national reference laboratory) but this is a relatively infrequent occurence.

5.37 In addition to providing a reference service for hospitals the reference laboratory provides the same service for other laboratories within the RTC. Thus the grouping laboratory would refer grouping problems, the antenatal laboratory problem tests etc. As the locus of serological expertise within the RTC the reference laboratory is often the place where reagents are produced if there is no separate laboratory to do this. This laboratory may be involved in screening donations for reagent material. Some reagent material is also identified as a by product of the serological investigations undertaken.

5.38 The amount of work undertaken by the reference laboratory will in part depend on the competence of the hospital laboratories in the region served. Large hospital laboratories develop their own expertise in serology and may have little need of the RTC service, several completely by pass the RTC and refer direct to BGRL if they have problems. Smaller laboratories may not have access to the skills (or for that matter the reagents) to deal with problem cases and therefore may make more use of the RTC service.

Other Serological Work

5.39 One other minor but relevant point is that three RTCs provide a routine crossmatching service for a local hospital. This means that all crossmatching is done for that hospital, not just the special references as described

above. One of the RTCs charges the district involved for this service. Routine crossmatching is a function of hospital laboratories and thus the funding of this small RTC activity may require attention if the BTS were to be funded centrally.

5.40 Donors with high levels of anti-D antibodies are identified so that their plasma can be sent to BPL for the production of anti-D immunoglobulin. This is required for Rhesus negative mothers who give birth to Rhesus positive babies as it prevents them producing anti-D antibodies which may give rise to problems in later pregnancies. RTCs collect anti-D plasma to different extents and there is little or no co-ordination to ensure that sufficient is collected throughout England and Wales to satisfy the demand for anti-D immunoglobulin.

5.41 RTCs may boost male volunteers with D-type cells to stimulate the production of anti-D antibodies. Oversight of such a programme, and the quatitation of anti-D antibody levels will usually be undertaken by either the ante-natal laboratory or the reference laboratory.

5.42 One centre tests donations from donors of negroid origin for indications of Sickle Cell anaemia. Appropriate donors are identified visually at the session by the clerk and "Sickle Cell Test" stamped against their name. The test is performed in the components laboratory. Any donations found to be positive are labelled and are not used for transfusions to infants. Donors found to be positive are also offered counselling.

Reagents

5.43 Diagnostic reagents are the basic tools of serology and are used in RTCs and hospitals in both the automated and manual grouping of blood. BPL Diagnostics produces a range of about 24 diagnostic reagents. The majority are made from plasma supplied by RTCs specifically for that purpose. BPL issues two monoclonal reagents at present and is the process of developing others. The cell lines upon which these monoclonals are based are grown on behalf of BPL by a commercial phamaceutical company. BPL refine, standardise and package the reagent. Plasma based reagents are supplied free to the NHS, the monoclonal products attract a charge on the basis that whilst plasma is donated free, the monoclonal cell lines have to be purchased and the cost of this should be recovered.

5.44 Every RTC also produces plasma based reagents. The extent of production varies but across the BTS nearly three-quarters of the range of BPL products are also being made in RTCs. Some RTCs are making half of the BPL product range, others only one or two products. In addition to the plasma based reagents at least two RTCs are also making monoclonal reagents and there is interest in other centres in moving into this field. Apart from reagents RTCs also make other human blood based products such as screening or standard cells and cell panels. Many RTCs also manufacture crystalloid solutions such as Papain, Liss etc.

5.45 About 30 staff are involved in reagent production at the BPL diagnostics laboratory at Oxford. BPL Diagnostics was, until the recent re-organisation of CBLA, part of BGRL and its diagnostic products are still widely referred to as "BGRL products". It is difficult to determine precisely how many staff are involved in reagent production in RTCs. In some centres it is a discrete function with a dedicated laboratory, in others it is one of a range of functions undertaken in a laboratory. We estimate that a total of about 60 staff are dedicated to reagent related work in RTCs.

5.46 In addition to the NHS (ie RTC and BPL) products there are commercial reagents available. It has not been possible to establish the relative market shares of BPL, RTCs and commercial companies because of the difficulty in obtaining production and usage quantities from RTCs and hospitals. The best estimate that we have been able to obtain is from BPL Diagnostics who reckon that their products have 50% of the market in volume terms. Their estimate of the value of their production in 85/86 was £2.5 million but it is extremely unlikely that this represent 50% of the cash value of the market. RTCs make a lot of the rarer and smaller volume reagents which are extremely expensive and consequently the total value of the reagent market is likely to be much more than £5 million. In addition to the "open market" there exists between RTC's a "swap shop" arrangement. RTC's informally exchange rare sera and reagents to enable local production or solve particular grouping problems and thus avoid the necessity to purchase commercially.

5.47 All RTC's screen donations with a view to, inter alia, discovering those with plasma which contains antibodies suitable for use as the raw material for reagent production. BPL reagent production depends on the supply of

appropriate plasmas from RTCs. There are no set targets for individual RTCs, consequently some, who undertake relatively little reagent production, may send larger quantities and better quality plasma to BPL than others who, being more heavily committed to reagent production, tend to keep the better quality and rarer plasma for their own use.

5.48 BPL reagents are available to both RTCs and hospitals. RTC produced reagents may be made available to hospitals or may be for use in the RTC only. Both RTC and hospital laboratories are free to use those reagents which they decide are most appropriate to the task: consequently most laboratories use a combination of RTC, BPL and commercial products. The factors governing the choice of products are cost, operational necessity and personal preference. The latter appears to be quite significant: we often found situations where the same reagent was praised in location A and berated in location B.

5.49 The development of RTC reagent production has been haphazard. Several years ago BGRL were the main producers. RTC production appears to have developed largely due to one, or a combination of, the following factors:

5.49.1 a reaction to fluctuations in the quality and/or continuity of the supply of the BGRL products, and the recent introduction of a charge for their monoclonal products;

5.49.2 the high price of commercial products generally and the ability of RTCs to utilise available donors, plasma and personnel;

5.49.3 staff interest in the serology of reagent production.

5.50 It is beyond the competence and remit of this study to comment on the quality of RTC and BPL reagents. Each producer claims that his product has its own particular qualities and is either better than, as good as, or cheaper than its rivals. We have to question however whether for example it is necessary or desirable to manufacture within the NHS some 8 variations of Human anti-B reagent; 9 variations of AHG reagent; or 11 variations of AB grouping serum. Or again it is questionable whether an RTC should be producing and issuing to hospitals a cell panel which those hospitals will not use because they consider it to be inadequate.

5.51 There appears to have been no objective consideration of the "make or buy" question in relation to reagent production in the NHS. It is assumed that NHS production is cheaper because the raw material for plasma based reagents is provided free by donors. In addition the progress in the development of monoclonal cell lines in at least two RTCs, and BPL, indicates that NHS production in this area could be cost effective. If production is to take place within the NHS it is necessary that it is rationalised to overcome the present duplication and plan for the future. Despite the fact that there are at least 3 established monocolonal reagent producers within the NHS several RTCs are now bidding for funds to move into this area. Unless there is some direction then the existing duplication of the plasma based products will be repeated, particularly as it estimated that some three quarters of all reagents used will be monoclonal in a couple of years time.

5.52 We suggest therefore that whichever organisational option is adopted the question of reagent production can and should be addressed. Production could be centralised at BPL Diagnostics and/or at one or two RTCs. Whatever decisions are taken it is vital to ensure that:

5.52.1 the production centre(s) has guaranteed supplies of the necessary quantity and quality of plasma on a planned and regular basis from RTCs;

5.52.2 the products are of the appropriate quality demanded by users and there is continuity of supply;

5.52.3 the producers have the organisational mechanisms to be responsive to the needs of the user.

Past failures in these areas are the main reasons why BGRL products lost the reputation which BPL Diagnostics is now striving, with some success to regain. The views we obtained during our fact finding interviews indicate that, whilst RTCs and Hospital laboratories will need to be convinced that the requirements above are satisfied, there is an undercurrent of goodwill towards NHS products. Failure to achieve these requirements will ensure that either the customer will go elsewhere, or encourage the continuation, and further development, of RTC cottage industries.

5.53 There is obviously potential for considerable saving in this area. BPL Diagnostics provisionally estimate that they could increase production to take up the majority of the NHS market with an additional 15-20 staff. Thus there is a potential staff saving from the estimated 60 RTC staff employed on reagent production of some 25 to 40 posts dependent upon how many staff RTCs need to retain for the initial identification of reagent material. In addition there will be economies of scale in production costs. The scope for future savings from avoiding commercial purchase cannot be assessed but is likely to be considerable.

Transfusion Microbiology

5.54 Transfusion microbiology is concerned with the testing of blood donations and other blood samples for the presence of organisms that either render the blood unsuitable for transfusion or identify it as useful for the production of clinical or diagnostic products. Whilst the precise name and functions of the laboratory concerned with this task may vary from RTC to RTC each has one or more engaged in this work.

5.55 There are three tests which are performed on every blood donation. These are:

5.55.1 a test for the presence of anti-bodies to the causative organism of Syphilis;

5.55.2 a test for the presence of Hepatitis B surface antigen (HBs Ag);

5.55.3 a test for the presence of anti-bodies to the HIV virus.

The latter test was introduced in October 1985.

5.56 The type of test and technique used vary from RTC to RTC as do the operational arrangements for doing the tests and associating the results with donations. Most commonly the tests are carried out the day after the blood has been collected. In some centres the pressure to issue blood or blood products (most frequently platelets) on the day of collection has led to arrangements being instituted for same day testing. In other centres some blood or products are issued before testing is complete and are labelled

accordingly. In these circumstances only known donors - ie. those who have donated before and were negative for HIV, hepatitis and syphilis on previous tests - blood is used and the tests are always carried out subsequently and the results notified to the clinician who transfused the blood or product.

5.57 For each of the three tests detailed above there are at least two, often more, kits available for performing the test. There are also two (or more) techniques for performing the tests. The test and technique chosen by any given RTC appears to be dependent on one or more of the following factors: cost of test; speed and convenience of test/technique; scientific preference of the medical or scientific staff; the way in which the test/technique fits in with other laboratory procedures.

5.58 For syphilis testing there are two main techniques - VDRL or TPHA. Mostly the test is done manually but one centre uses an automated VDRL technique which is carried out on the autogrouper at the same time as the donation is grouped.

5.59 Testing for HBs Ag is either by radio-immunoassay (RIA) or else by enzyme linked immunosorbent assay (ELISA). Until recently the former method was almost universal throughout the BTS and the kit used was produced by BPL. Four centres have now switched to the ELISA method. It is interesting to examine briefly the origin of this test and its price since this throws some light on both the relationship between RTCs and CBLA and CBLAs pricing policy and that of the commercial sector.

5.60 Prior to the introduction of the BPL RIA test for HBs Ag there was concern at BPL about the sensitivity of the tests in use at RTCs. BPL was worried that the tests used by RTCs might not be screening out all infected plasma. BPL therefore developed their own RIA test (with help from RTC laboratories) and proposed that they test all the plasma they received. This proposal was not well received by RTDs and a compromise was reached whereby RTCs would use the RIA test developed by BPL. In this way the Director of BPL was satisfied that the quality of the plasma being processed was not compromised. The original proposal was that BPL would charge a nominal amount for the test to recover their packaging costs etc. This amount so undercut the commercial companies price that they protested and BPL were forced to charge a price closer to the going market rate.

5.61 The majority of RTCs using the ELISA technique for HBsAg testing use a kit from the Wellcome Foundation (Wellcozyme). These have become more attractive since the ELISA technique is generally accepted as being as sensitive as RIA, but doesn't require the handling of radioactive material and does not require capital expenditure on the specialised equipment required for the performance of the RIA test. Also, Wellcome sell their HBs Ag and HIV tests as a package with discount if the two are taken. The price of the ELISA kits now available have recently forced BPL to reduce the price of its RIA kit from 24p to 12p which ironically is much nearer the price they originaly intended to charge. A number of RTCs mentioned that they would have abandoned the RIA test for an ELISA test had the price of the former not been halved, others are quite happy with the test and had no plans to change.

5.62 Testing for HIV anti-bodies is universally done by an ELISA technique, the majority of centres using the Wellcozyme Test. Other kits in use include those made by Organon and Dupont. The introduction of the HIV antibody test is one of the areas where the RTDs and their centres have successfully collaborated. Various kits were trialled by PHLS who recommended the Organon and Welcome kits for extended trial in selected RTCs. Both were found to be satisfactory and RTCs were able to choose that most suited to their needs although as noted above, at the time of the study Welcome had the major share of the market. The introduction of the test was co-ordinated so that testing commenced on the same date in all RTCs.

5.63 For each of the three tests arrangements need to be made to deal with donors who are found to be positive. In all centres one or more of the consultant medical staff have been trained in AIDS counselling. The centre will deal with initial counselling but the donor is referred to an appropriate treatment centre for long term care. Cases of syphilis and Hepatitis B are generally notified to the donors GP although one or two centres take a more active role in dealing with infected donors. All positive results of the above tests are independently confirmed by another laboratory, often, but not always, the PHLS.

5.64 Apart from testing donations Transfusion Microbiology Laboratories are also involved in testing other blood samples eg all ante-natal samples that arrive at RTCs for investigation are tested for syphilis and a proportion for Hepatitis B.

5.65 Apart from the three "universal" tests described above there are a range of other tests that are carried out to a varying extent in RTC laboratories. These are tests for:

5.65.1 Cytomegalovirus antibody (CMV test);

5.65.2 Malarial antibody;

5.65.3 Hepatitis B antibody;

5.63.4 Tetanus antibody;

5.63.5 Varicella/zoster antibody;

5.63.6 Rabies antibody;

5.63.7 Mumps antibody;

5.63.8 Pseudomonas antibody

CMV Test

5.66 The cytomegalovirus occurs in approximately 50% of the population. It generally produces no symptoms in healthy persons but can be dangerous in certain patients, particularly those whose immune system is suppressed, eg. transplant patients or new born babies. There has been increasing demand for CMV negative blood and blood products for these types of patient. Most RTCs can now supply CMV negative blood on request and all plan to provide this service routinely in the near future.

5.67 The introduction of CMV testing has been largely unco-ordinated although this is due in part to the unequal rate of development in different regions of the specialities requiring CMV negative blood and products. There is no universally used test and each centre has introduced testing at different times and on a different operational basis. Some centres have initially screened a large number of donors to provide a core of CMV negative donors for future use. Others have built up the donor base gradually by screening a set

number of donors per week. Where CMV testing is well established the blood bank normally contains a stock of CMV negative blood and blood products. Where CMV testing is less established CMV negative blood may have to be specially requested by clinicians so the RTC can mount a screening exercise to provide it.

Malaria Test

5.68 The red cells of donors who have suffered from malaria have to be discarded but the plasma can be used. Thus the blood of donors, who at the time of donation state they have recently been to an area where malaria is endemic, must be specially marked at the session and subsequently only its plasma content can be used. This inevitably means that some red cells are wasted since not all donors who travel to malarial areas become infected.

5.69 Two RTCs in large population centres with sizeable immigrant populations found they lost a significant number of red cell donations through this precautionary measure. A test was therefore developed for malarial antibodies. Donors at these centres who identify themselves as at risk from malaria can therefore be screened and their red cells need only be discarded if they are found to be positive.

Test for Hepatitus B, Tetanus, Varicella/Zoster, Rabies, Mumps and Pseudomonas Antibodies

5.70 Unlike the test for HBs Ag detailed at paragraph 5.59 these are not tests to screen out blood that could transmit infection. They are rather tests to identify donors who have a sufficient level of the relevant antibody in their plasma to make it worth sending to BPL for conversion into specific Immunoglobulins. The tests are a two stage process: first donors are screened (often at random) for the presence of the antibody; those found to be positive are then further tested to quantitate the strength of antibody in the plasma. Donors found to have high levels of antibody are invited to become plasmapheresis donors and the plasma is collected in this manner so long as the high titre of antibody is maintained. Some centres also quantitate CMV antibody level for the same purpose. Whilst donors can be screened at random for the above antibodies quite often specific groups are identified who are likely to have the antibody. Thus those, such as vets, who

are regularly immunised against tetanus because of their work provide a good source of tetanus antibody. Similarly customs staff at ports and airports are a good source of rabies antibody. Donors who volunteer that they have recently recovered from mumps, chicken pox or shingles may be screened for mumps or varicella/zoster antibodies. Finally, some RTCs provide plasma to BPL for the production of immunoglobulin for use with measles vaccine.

5.71 The RTCs have no targets as to the amounts or types of specific plasma they should produce. Centres tend to concentrate on one or two specific plasmas rather than to collect the whole range. Whilst most are committed to collecting specific plasma it is a fairly resource intensive procedure and inevitably when resources are short the collection can be reduced or temporarily suspended. Thus BPL cannot be certain of the amounts of specific plasma they can expect on a month to month or even year to year basis. This of course makes planning difficult. Not all centres quantitate the strength of antibody in a donation prior to despatch to BPL so the central laboratory receives plasma of variable quality.

5.72 Where BPL finds itself short of a specific plasma all it can do is appeal to RTCs to collect more and hope they respond. It would seem adventageous to both RTCs and BPL if the collection of specific plasmas were to be planned jointly. The yearly requirement for specific plasma could be determined and then centres set targets for production.

5.73 The current ad hoc arrangements for the collection of specific plasmas mean that not all RTCs, and therefore regions, contribute equal resources to the task. To date there has been no indication that has caused disquiet in RHAs. It is however questionable whether this attitude will continue as RHAs become more cost conscious. This obviously raises similar considerations as those discussed in relation to self sufficiency generally. In the absence of reliable costing information it is not possible to be precise but the resource intensive nature of this work suggest that it is unlikely to be cost effective for each region to seek to be self sufficient in the collection of specific plasmas even if this were operationally viable. A coordinated approach allowing either concentration of all specific plasma collection in one or two centres or each centre having responsibility for particular plasmas would appear to offer an effective way forward.

Bacteriological Testing

5.74 Bacteriological tests are aimed at establishing whether blood, blood products, materials, equipment or working environments have been contaminated by harmful bacteria. It is thus essentially a quality assurance procedure. The extent to which bacteriological tests are carried out varies enormously from RTC to RTC. Most RTCs have some programme of culturing samples from outdated blood and blood products to monitor sterility. Other measures may include:-

5.74.1 testing air samples from work areas, particularly lamina flow cabinets and aseptic suites;

5.74.2 testing samples taken from swabs used to sterilise the venepuncture site on donors arms;

5.74.3 testing the sterility of various equipment eg. centrifuge buckets;

5.74.4 testing the sterility of disposables such as blood packs.

The list is illustrative rather than exhaustive.

5.75 The PHLS is often used to identify any bacteria that are cultured. Where harmful bacteria are identified procedures may be reviewed and changed. If this type of work is carried out it is usually the responsibility of the Transfusion Microbiology laboratory. However in some centres responsibility for it is sited elsewhere.

5.76 An increasing awareness of the need for quality assurance and good manufacturing practice is developing in RTCs. At the moment bacteriological testing is developing piecemeal and not all directors agree on the necessity for it. It can be expensive to perform and there could be benefits from developing common standards and testing protocols. This issue is discussed further at paragraph 5.112 et seq in relation to quality control.

Summary

5.77 As mentioned at the outset of this section tests, techniques and operational arrangements vary considerably from RTC to RTC and reflects the

differing opinions on the necessity for particular tests or the extent to which they should or need to be done. Since no RTCs identify the cost of transfusion microbiology separately in their accounts it is impossible to compare costs or efficiency from RTC to RTC except by very crude measures.

5.78 We have roughly identified where possible the number of scientific staff employed in transfusion microbiology at each RTC. The ratio of donations processed per member of staff ranges from 11,000 : 1 to 33,000 : 1 ie very roughly the most efficient RTC appears about three times as effective in staff resource terms as the least efficient. Of course these figures take no account of the extent of screening for specific plasmas or bacteriological work. However, the extent of the difference suggests that there would be advantage in seeking to identify the reasons for it.

5.79 We accept that when determining which test or technique to use cost cannot be the only factor considered. The quality of the test and how it fits in with other laboratory procedures and existing equipment must also be considered. We also recognise that there can be dangers in requiring all centres to test using the same materials, equipment and procedure. However, once management information is available that allows comparison of performance between RTCs it should be possible to ensure that the correct balance is struck between these factors and greater uniformity achieved.

5.80 We were struck by the duplication of effort involved in evaluating new tests or techniques. With the notable and commendable exception of the introduction of the HIV test there is relatively little co-ordination in test evaluation. This is quite an expensive process since it involves the parallel testing of a fairly large number of donations with the existing and new tests. The success of the collaboration on HIV testing indicates the way forward and we think that it would be advantageous, and offer the potential for resource savings, if all test evaluation was rationalised and co-ordinated.

Blood Products

5.81 Each RTC has a blood products laboratory although its title may vary slightly. These laboratories generally only cover the production function and tend to be the largest in terms of staff numbers in most RTCs. We estimate that about 225 staff (qualified and unqualified) are devoted to this function equivalent to approximately 17% of the total scientific and technical

establishment in the BTS. The size of the laboratory varies between RTCs and depends to an extent on the number of donations handled and the number and mix of products made. The smallest product laboratory contains 6 staff the largest 26. The largest laboratory deals with 1.5 times as many donations as the smallest and produces 1.1 times as many products. The largest laboratory makes 3 products that the smallest does not. The trend amongst clinicians is now to give patients whichever of the components they require rather than to simply transfuse whole blood. This has led to more and more of the blood collected by RTCs being processed. Add to this the demand for plasma for fractionation at BPL (see paragraph 6.49 et seq) and it is not surprising that all RTCs now process over half the blood they collect and some process as much as 90%.

5.82 Simplistically the task of the blood products laboratory is to separate whole blood into various combinations of its four main components - red cells, white cells, platelets and plasma. More than 20 products are now produced by RTCs. No one centre produces the whole range but some products are similar and to a degree interchangeable in clinical use. The range of products produced by an RTC reflects partly the demands of clinicians in hospitals and partly the RTC's willingness, or ability, to make them. Tables 9-12 (see pages 154-157) show the numbers and cost of each blood product made in 1985/86 broken down by region.

5.83 The starting point for blood processing is the donation, normally 450 mls of blood and 63 mls of anti-coagulant. Thus the total volume of a unit before processing is about 500-520 mls of which approximately 200 mls are red cells and the remainder a mixture of plasma and anti-coagulant. From this source a range of products may be made. The full range of products cannot be made from one donation: from about 2 million donations (85/86 financial year) nearly 4 million units of product were made - an average of about 1.9 units of product per donation.

5.84 The products fall broadly into two categories

5.84.1 large volume products made by what may be termed production line processing. These include plasma reduced blood (PRB), concentrated red cells (CRC), SAG(M) red cells, platelets and fresh frozen plasm (FFP);

5.84.2 Small volume specialised products such as filtered blood, saline washed blood etc made by laboratory processes of some complexity;

5.85 In addition whole blood is also issued. It is somewhat of a misnomer in that this term is used to cover three products: units of blood which have not been subject to any processing; units of blood from which the platelets have been removed; and units of blood from which cryoprecipitate has been removed. Both platelets and the active constituents of cryoprecipitate deteriorate quickly in stored blood so that after about 3 days there is little difference in the therapeutic qualities of these three products. Hence use of the same term to cover them. Fresh whole blood, which is generally blood transfused within 24 hours of collection, is also included under this head for record keeping purposes. It requires no special processing.

5.86 In volume terms in 1985/86 about 40% of donations collected were issued as whole blood, 30% as PRB/CRC and 30% as SAG(M) (see Table 13 page 158). About 23% of donations were used to make platelet concentrates. On the other hand filtered blood, for example, represented about 0.5% of donations collected and buffy coats about the same. The small volume products although labour intensive do not significantly affect the ability of the RTC to meet the demand for large volume products whereas the relationship between the amounts of each large volume product that an RTC can make is complicated.

5.87 The basic requirement of the products laboratory is to strike a balance between satisfying the demands from hospitals for products whilst at the same time maximising the harvest of plasma that can be sent to BPL for fractionation. What products can be made from a donation is determined to an extent by the type of pack into which a donation is bled. The major difference in packs is the number of satellites attached to the main collection bag. This ranges from 0 to 3 and they facilitate the asceptic separation of blood components. Production planning has therefore to include decisions as to which of 15 or more packs donors should be bled into.

5.88 Instructions to the team in this regard may have to be given up to a week before the session is held but in most cases a days notice is sufficient. Several RTCs use radio pagers or radio telephones so that teams can be contacted at sessions and in these circumstances the products laboratory can alter the pack configuration during a session in response to

variations in product demand. The more "satellites" a pack has the more flexible it is in terms of the number of products that can be made from the blood in it, but it is also more expensive. For example a single pack can only be used for whole blood donations (or open process products such as filtered blood); double packs can be used for PRB or CRC and FFP also a triple pack can be used for platelets, CRC and FFP. Quad packs are the most expensive but most flexible in that they may be used for the greatest range of products.

5.89 In planning what products to make on a daily basis the laboratory has to take account of several, to some extent conflicting, factors. Firstly an assessment has to be made as to how many of which products hospitals will require. Those with a long shelf life (all large volume red cell products generally have a shelf life of 35 days; frozen products can last up to a year) can be stockpiled and production requirements assessed by comparing current stock with normal demand. Those products with a short shelf life, particularly platelets, are more difficult in that the flexibility to cope with that element of demand which is unpredictable is less. Secondly each unit of platelets and FFP for hospitals produced means less plasma available for fractionation at BPL. Thirdly it is necessary to make the most economic use of the various packs available.

5.90 We have observed a number of differences between centres in products, methods and policies which are, in our view, of significance in relation to the consideration of the organisation of the BTS and also the relative cost efficiency of blood products laboratories. We have discussed in earlier paragraphs the skill mix of staff in the scientific and technical side of the BTS. Several of the "production line" tasks in the products laboratory appear suitable to semi-skilled staff under supervision eg production of plasma and platelets. There are however wide variations between the RTCs in the proportion of such staff deployed in product laboratories ranging from four centres who use none through to centres where two thirds to three quarters of the staff are laboratory assistant grades.

5.91 There are differing attitudes, which may or may not be shaped by customer's views, towards particular products eg

5.91.1 the proportion of whole blood issued by RTC's ranges from 15% to more than 60%, (see Table 13 page 158);

5.91.2 some centres issue paediatric whole blood in multipacks so that small amounts may be aseptically separated from the donation for transfusion. This facilitates the use of one unit for up to four transfusions. Other centres make no special arrangements for such blood and claim that it is more economic for the hospital to transfuse whatever portion of a whole blood unit is required and discard the remainder than to provide a multipack;

5.91.3 some centres do not issue filtered blood because they take the view that it can be made in a hospital laboratory and since it is staff intensive to make it is not a cost effective product for the RTC to produce particularly as the level of demand is so low;

5.91.4 most RTCs produce platelets with a 5 day shelf life and expect hospitals to pool the units to make up a dose. Several centres pool platelets in the RTC thus reducing the effective shelf life to 12 hours;

5.91.5 the recognised shelf life for whole blood and red cell products is 35 days. Two centres give their red cell products a 28 day shelf life purely for operational reasons.

5.92 Most centres collect some of their FFP for fractionation in the "wedge" pack, a pack specifically developed for this purpose by BPL and a manufacturer. Plasma collected into this type of pack cannot be used for any purpose other than fractionation. Use of this pack therefore considerably reduces an RTCs operational flexibility. Two RTCs do not use these packs on the grounds that to do so would so reduce their production flexibility as to prejudice their ability to meet hospital demand for products from the available donations.

5.93 There are differences in the composition of products from region to region. This is most noticeable in the area of plasma harvesting where the volume obtained varies from 180 ml to 230 ml per donation when SAG(M) is not used and from 240 ml to 270 ml when it is. Several RTCs issue a product list to hospitals detailing not only their products but also the content of the products. The extent of Quality Assurance (QA) performed on products varies. Most centres do some but there are no standard protocols and the extent may be affected by the demand for products. At present there are no generally

accepted techniques for the non-destructive testing of platelets so RTCs are understandably reluctant to QA too many since each one tested is one less available for issue. The whole question of QA/QC is discussed at paragraph 5.112 et seq.

5.94 Some RTCs contain the work of the products laboratory between 9am - 5 pm on weekdays others occasionally require overtime during the week. Several run regular evening shifts of part-time staff and may have Saturday morning shifts. All have "on call" arrangements to deal with emergency situations. Evening and weekend shifts have generally arisen for two reasons. Firstly, the demand for platelets, which have to be made within a few hours of donation, is such that insufficient blood is available during the day to meet production needs. Consequently the evening shift is employed to process the blood which has been collected during the afternoon. Secondly, plasma which is harvested and frozen within 6-8 hours of donation tends to have its Factor VIII content preserved more effectively than when it is harvested later. Consequently some RTCs endeavour to ensure that the majority of their plasma is "8 hour plasma" by providing processing capacity in the evenings.

5.95 It is not possible to comment on the relative efficiency of production between RTCs without sound management information and a detailed examination of processes. We have attempted to compare available statistical information which leads to the conclusion that differences in efficiency do exist between RTCs. For example the number of products processed per member of laboratory staff per year ranges from 12,000 to 35,000, virtually a threefold difference in productivity. Also the processing costs per donation range from £1.27 to £4.84 (see Table 8 page 153). Whilst we have expressed misgivings as to the reliability of these figures a range of this magnitude points to underlying differences in efficiency that need to be examined further. It is to be hoped that with an improved management information system meaningful performance comparisons can be made and the causes of differences in performance identified and tackled.

Tissue Typing

5.96 Tissue Typing (TT) is one of the newer specialties and has developed at a different pace in different regions. In all but two RTCs a TT service of some sort is provided. In some regions the RTC has been designated as the regional centre for TT, in others the RTC is only involved in particular

aspects of the function and other aspects are the responsibility of one or more hospital laboratories. As with other developments there does not always appear to have been a co-ordinated approach or an objective consideration of the most suitable location for the service. Development appears to have been the result of a particular interest either on the part of the RTC or clinicians elsewhere.

5.97 Part of TT work involves HLA typing of donors or patients and identification of Anti-HLA antibodies. The HLA system is in some senses like a blood grouping system eg there are HLA-A, HLA-B, HLA-C types etc and there are antibodies to these types. The aim of HLA typing is (like blood grouping) to attempt to match the HLA types of donor and recipient to avoid transfusion or transplant reactions. The difference is the HLA system is larger (there are more types) and the laboratory techniques involved are nearly all manual and labour and skill intensive.

5.98 The work done in TT laboratories divides broadly into three categories. Firstly work done to support the blood transfusion task of the RTC. For example, HLA typing of donors so that HLA matched blood products (particularly platelets) can be provided; HLA typing of donors to provide a panel of typed cells for the screening of sera for anti-HLA antibodies; screening of sera to identify those with HLA antibodies that may be suitable for use as TT reagents; and investigation of transfusion reactions where anti-platelet, anti-granulocyte or anti-plasma protein antibodies are suspected - this is similar to the serology reference service (see paragraph 5.36) and may take place after serological investigation has failed to reveal a blood group reaction.

5.99 Secondly what might be termed a Regional TT service. For example:

5.99.1 TT of patients requiring organ transplants, donors or cadaveric organs and monitoring of the patient post transplant. This will include bone marrow transplant patients and donors, as well as kidney, heart etc transplants. Post transplant monitoring is, in some regions, a function of the laboratory in the hospital which carried out the operation;

5.99.2 disease association studies - certain HLA types are associated with diseases and HLA typing of the patient may be an aid to diagnosis. Opinion varies as to the extent this should be provided as a routine service, the only generally acknowledged association at present is that of HLA type B27 with ankylosing spondylitis;

5.99.3 family studies.

The amount of work generated in this area is governed to a large extent by the amount of transplantation activity within the region. It is likely therefore to be an area of further growth as provincial regions begin to provide, or expand existing, transplant services.

5.100 Thirdly work done in support of national objectives and institutions. This may include

5.100.1 the typing of unrelated bone marrow volunteer donors for the national panel. This panel is held at the United Kingdom Transplant Service (UKTS) based in Bristol. The number of volunteers, if any, typed is for individual RTCs to decide. There are no quotas and the panel therefore grows haphazardly. It is also in competition with the Anthony Nolan Appeal which is a charity running its own panel;

5.100.2 identification of HLA typing sera for inclusion in the national serum bank at UKTS - again RTC participation is voluntary;

5.100.3 research - several TT laboratories are actively engaged in research, either in isolation or collaboration with hospital and university laboratories within the region and on a wider national scale.

5.101 Not all RTCs engage in every aspect of TT activity. We estimate that nationally about 75 staff are deployed ranging from 3 to 16 in each RTC involved. Whilst variations in the work undertaken by each TT laboratory will account for some of the difference, the extent of the range indicates still further the varying attitudes towards staffing between RTCs and Regions and points up yet again the difficulties in attempting comparison in the absence of reliable work measurement and management information.

5.102 It is beyond our remit to decide on the most appropriate location for a TT service however consideration of the organisation and funding of the BTS requires that some thought be given to the question. Excluding Bristol RTC, (whose TT function is, in effect, carried out by UKTS) one RTC has no TT capacity yet we must assume that the region manages to provide the required level of TT service from a hospital base. If the demand for HLA matched blood components continues, or indeed increases then RTCs will need some TT capacity to meet it. There would appear to be some logic in RTCs, experienced as they are in dealing with donors, co-ordinating the national panel of unrelated bone marrow donors. They could however merely co-ordinate the administration without necessarily doing the typing. Investigation of transfusion reactions is, as noted above, in effect an extension of the serological reference service of the RTC and would be best sited there. All the other tasks could be, and in some regions are, carried out in hospitals, or a hospital specialising in the work. In addition, the volume of blood from donors and, in some cases, ante-natal samples passing through the RTC, makes them well placed to identify TT reagent material since multiparous women are a particularly good source of HLA antibodies. The organisational considerations are in effect those which we identify in relation to ante-natal testing at paragraph 5.34.

Research

5.103 The term research covers a whole range of activity within the BTS. On the one hand there is what might be termed "pure" research which is geared to developing our fundamental understanding of biological, chemical or physical processes etc. On the other hand there is "developmental" research which may involve developing existing techniques or processes which are well understood or, on perhaps a "higher level", work which researches the properties or reactions of known substances, products or groups of people which is directed towards achieving better, more effective or safer products, processes or treatments.

5.104 We would not wish to enter into a debate on precise definitions of what is or is not research (pure or otherwise). Suffice it to say that for the purposes of the study we would define "pure research" in the BTS as something which whilst related to blood or its components, is not directed to resolving a particular problem within the BTS, may not even have been triggered by such

a problem and the results of which may not be of any immediate relevance to the BTS. Anything else, be it research or development, which is triggered by a problem or situation with in the BTS and is geared to resolve that problem, even if in the course of doing so it uncovers the potential for a channel of "pure" research, we define as R&D.

5.105 An example of pure research would by our definition be the work on the red cell membrane at Bristol RTC. Examples of R&D would be the wide range of work or the properties and make up of platelets which is being conducted in several centres and the work which is being done to make virology tests either more sensitive, faster or cheaper.

5.106 All RTCs are involved to a greater or lesser extent in R&D. It forms by far the great majority of the research undertaken and is the aspect which is, in our view, particularly relevant in the consideration of the organisation of the BTS. Both medical and scientific personnel are involved and the approach to the subject may be either medical, scientific or a combination of the two. It may be contained within a centre or conducted in collaboration with other RTCs, hospitals or universities. Six RTCs contain a laboratory which has the term research or R&D in its title and across the BTS some 16 scientific and technical staff are specifically identified as being deployed on these activities. Despite this there is only one RTC which has R&D monies identified in its budget. In all others research tends to be supported on money and staff either saved from or hidden in operational laboratory budgets. For example many individuals or groups undertake R&D projects as an adjunct to their main or specified activities. It is therefore impossible to assess the extent of investment (or lack of it) in R&D in the BTS but it is undoubtedly more than the 16 staff identified. Both BPL and BGRL also conduct research, both internally and in collaboration with RTCs. This function is recognised within their budgets and by the existence of an R&D department.

5.107 Until recently there was no co-ordination of R&D in the BTS. A committee has now been established with the aim of co-ordination but as it has no funding function it may have difficulty in establishing its policies and exerting any influence within the BTS.

5.108 The lack of co-ordination has meant that there can be duplication of effort with the consequent waste of resources. It also means that there is no formal mechanism to initiate R&D that is considered to be necessary particularly where no known interest exists. The R&D carried out in RTCs at present tends to be in part the result of the doctor's or scientist's particular interests.

5.109 There seems little argument that R&D needs to be carried out in the BTS. In it's areas of specific scientific interest and expertise it is difficult to see who would do the R&D if the BTS did not. Given the limited resources available R&D must be co-ordinated to get value for money and ensure dissemination of results.

5.110 In considering R&D we would suggest a number of areas need to be looked at:

5.110.1 does every RTC need to do R&D?;

5.110.2 project planning and control - this is non-existent in some RTCs and rudimentary in others;

5.110.3 ownership and exploitation of discoveries, inventions etc of commercial value;

5.110.4 identification of areas of research to be undertaken.

5.111 Whilst there are dangers in an over-bureaucratised R&D policy in the long run better co-ordination should benefit the BTS. A balance needs to be struck between encouraging individual iniative, and hence sustaining the interest and the commitment of scientists and doctors in the BTS, and the collective needs of the BTS. This may mean curtailing or limiting some projects in favour of others that have more importance to the BTS nationally. The extent to which R&D may be effectively co-ordinated will depend to some degree on the organisational structure of the BTS. It would be easier in a centrally managed organisation, more difficult, but not impossible under the existing structure.

Quality Assurance and Control

5.112 External quality assurance for serology at both RTCs and hospitals has until recently been provided by the NEQAS scheme run by BGRL. The scheme is at present suspended due to lack of staff to run it at BGRL but it is hoped to restart it in due course. Concern has been expressed as to the effectiveness of the scheme, because participation is voluntary, and the follow up procedure if an RTC or hospital gets poor results does not appear to have operated consistently in the past. In the temporary absence of NEQAS some RTCs have organised their own schemes for hospitals in their area. With the increasing emphasis on quality assurance RTCs are considering whether internal proficiency checks on grouping ability should be introduced. On the microbiology front there is little in the way of external monitoring of standards. All RTCs take part in a PHLS scheme to quality control HIV testing. Other schemes are run by PHLS, on similar lines in that participation is voluntary. There are no other nationally organised forms of external QA/QC which operate within the BTS. The Medicines Inspectorate has in recent years been conducting a programme of inspections of RTCs. These have been instrumental in promoting the value of QA/QC procedures and have also resulted in the upgrading of facilities in some RTCs.

5.113 Internal QA/QC is an issue which is at present the subject of some debate within the BTS. There are no national or service wide standards to which all RTCs adhere or are required to adhere. From our discussions it is apparent that there is no agreed definition of what such standards should be or what aspects they should cover. One view is that QA/QC should cover every aspect of an RTCs activity ie not only ensuring that the products, both therapeutic and diagnostic are what they are said to be and do what they are said to do, but also that the environment in which they are made, the equipment used, the procedures followed and the way in which blood is collected is controlled. A committee of BTS staff has been set up to look at all aspects of QA/QC.

5.114 No RTC currently undertakes QA/QC to the extent described in the preceding paragraph. Some centres are tackling some aspects (see the previous paragraphs in relation to microbiology and blood products) but in reality many centres operate little in the way of QA/QC. It would seem reasonable to argue that if a QA/QC procedure is necessary in one RTC then it should also be

carried out in all centres to ensure consistency of service and product. The range of QA/QC conducted appears to have developed at the behest of individual directors and without consideration of the necessity or desirability for overall operational uniformity. About half of the RTCs have a laboratory which has the term QA or QC in its title, in the remainder it is a sub function of the products laboratory itself or some other laboratory. The one common thread that has emerged from our discussions is that everybody within the BTS thinks more QA/QC should be done.

5.115 It has been suggested to us in some quarters that there will be pressures for a co-ordinated policy because of developments in the product liability laws and the demands of good manufacturing practice. Such pressure might be inevitable if CBLA develops a commercial market for its products and requires licences as apparently the licencing process could require guarantees on the source raw material blood. Whilst recognising that this is merely hypothesis at present it demonstrates the QA/QC link between RTCs and CBLA. BPL Therapeutics quality control all plasma received yet several RTCs also do this before it goes to BPL. It would appear that this is unnecessary duplication and suggests the need for an agreed and co-ordinated policy.

5.116 It is likely that any development in QA/QC will have resource implications. It is not possible at this stage to assess what, if any additional resource would be required. The largest number of staff identified as being devoted to QA/QC in any RTC is 5 but that centre is of the view that this resource is inadequate. If the resource required in each RTC was five then some 70 staff would be required across the BTS. Although we are unable to precisely quantify the resources presently deployed we estimate that this would mean of the order of a threefold increase.

6. SUPPLY & DEMAND

Synopsis

Taken in overall national terms we conclude that the total number of donations required will at most rise at a modest rate that can be easily contained with the total number of potential donors available if all centres achieve the bleeding performance presently achieved by the best. The major problem is that the readily collectable blood is not where the supply problems are. The resolution of these problems will depend entirely on the formulation of clear policies and comprehensive arrangements. This will require either mechanisms within the existing organisational structure or organisational change. The existing ad hoc arrangements which result in for example an estimated 10,000 units of surplus blood being unused last year largely because it was not of a blood group which could be utilised by importing centres, will not be adequate.

6.1 The demands on RTCs are twofold: firstly the need to satisfy the demand from hospitals for blood and RTC made blood products; secondly the need to supply plasma to BPL in accordance with their allotted targets. In determining the total amount of blood which needs to be collected the two factors are inseparable. However to understand their organisational impact it is necessary to examine them in isolation.

Hospital demand for blood and RTC made blood products

6.2 The comments in this section exclude platelets - these are discussed separately at paragraphs 6.13-6.19.

6.3 In terms of meeting hospital need most regions are "self- sufficient". They can generally cope from within their own blood collection programmes and, at times of crisis, make up any shortfall by calling on other RTCs. However two of the London centres - Tooting (SE and SW Thames) and Edgware (NW Thames) - are unable to meet their own needs and rely on regular assistance from other RTCs and Scotland. We estimate that the level of support provided to these two centres was in excess of 40,000 units in 1985/86. About half of this supplement came from other regions in E & W and half from Scotland. There are boundary problems between the 3 London centres which exacerbate the balance of need but the overall supplement of 40,000 units which was required equates to nearly 10% of the total blood collected in SE, SW and NW Thames Regions.

6.4 It is important to recognise that at present regional self sufficiency does not mean meeting all requests made by hospitals. All RTCs, whether self sufficient or not, are to a greater or lesser extent regulating the demands which are made on them by controlling the amount of blood and products they issue. The exercise of this control is motivated by one, or a combination, of the following factors:

6.4.1 clinical - RTC Medical staff persuade their hospital colleagues that a particular product or dosage is, or is not, appropriate in respect of a particular patient or set of circumstances. They also disseminate general information and advice on the therapeautic use of products;

6.4.2 supply - when RTCs have insufficient supplies of a particular product issues are rationed either "across the board" or by a critical examination of each request;

6.4.3 production - a range of products may be made from a unit of blood. Each production process has a cost and maximising production of one or a range of key products affects both the capacity and willingness to produce the full potential range regardless of the RTC's relative "self sufficiency" position.

6.5 It is apparent that these factors also condition the pattern of demand from hospitals. RTCs with a similar customer base are providing a slightly varied range of products eg there are at least 3 RTCs who do not provide filtered blood and more than half of the RTCs do not provide paediatric whole blood. Yet the hospitals which we visited generally expressed satisfaction with the range of products available from their RTC. Conversely we also discovered examples of RTCs meeting demand for products because of customer pressure despite the view of the RTC director that the product should not be provided.

6.6 There is evidence to suggest that some hospitals inflate their requests because they suspect that the RTC will allege a shortage in order to control issue and that some RTCs will deliberately haggle with hospitals because they suspect that requests are inflated. Some RTCs take the view that "if we have got it they (the hospitals) can have it" and issue accordingly.

6.7 We conclude therefore that:

6.7.1 the absence of production does not necessarily indicate an absence of demand;

6.7.2 restriction of supply does not necessarily indicate an inability to meet demand;

6.7.3 the existence of demand does not always indicate need. Consequently because "demand" ie. either the particular products requests or the quantities of product requested by hospitals is a rather intangible concept it does not and should not, in isolation, form an adequate criteria by which to determine the level of blood collection activity.

6.8 It is therefore necessary to attempt to differentiate between "need" and "demand". We sought to identify instances where patient care was adversely affected by the failure, for whatever reason, of the RTC to meet demand. This could be manifested in, for example, the postponement or cancellation of routine operations, inability to cope with emergencies or, in the extreme, patient death; fortunately we discovered no examples of the latter. Generally those regions which are self sufficient rarely had any such incidents. Even in those regions which regularly require to import blood the incidence of postponement and cancellation was said to be fairly frequent but not high. In NW Thames the director suggested that she required an additional 20-30,000 donations per year to satisfy demand but could meet need with the existing 10,000 unit supplement from other regions. Given the absence of any major evidence to the contrary it is reasonable to suggest that a more realistic measure of the requirement for blood and products in England and Wales is that which the BTS supplies to that area. The major problem with supply and demand is that at present the demand problems are not in those areas of surplus supply.

6.9 The indications are that the requirement for most products increases in a linear relationship to general medical advances and local developments. Progress has been on such a scale as to enable it to be assimilated within collection programmes. Such problems as do occur tend to be associated with planning weaknesses or communication breakdowns which result in RTCs having

demands placed upon them for which they have had no opportunity to plan. These problems are overcome in the short term by expedient measures until the new demand can be accommodated. With the exception of platelets which are discussed at paragraphs 6.15-19 we have been unable to discover any national developments which are, in the forseeable future, likely to cause acceleration in the growth of the requirement for blood. In the past ten years blood collection has increased by a total of about 16% ie an average of 1.6% per year. It should be noted however that it in fact declined in 1984/85 by about 2% (see Table 14 page 159 for the number of donors bled 1982-1985). For the purposes of assessing future requirements we have assumed that the overall rate of growth ie 1.6% per year will continue. This being so it would indicate a need for about 2.29 million donations by 1991.

6.10 There are indications that two factors may cause the rate of growth in demand for blood and blood products to decline. It has been suggested that the fear of Aids has engendered a degree of caution amongst clinicians in relation to their use of blood. Anecdotal evidence received towards the end of the study period suggests that some previously pressured RTCs are for the first time in years experiencing a surfeit of blood. Furthermore the development of autologous transfusion, even if it is on a relatively small scale, may also reduce the demand for BTS blood, although not necessarily BTS involvement in the collection process. Although it is too early to say whether either of these factors will have any long term significant impact they do lend further weight to the conclusion that a level of about 2.2 - 2.3 million donations per year will be sufficient to meet hospital need nationally for the next five years.

6.11 All but three RTCs are self sufficient and in 1985/86 half of the RTCs were each able to "export" more than 1000 units to other regions (see Table 15 page 160 for major blood movements). Exports are not usually units of whole blood but concentrated red cells from which both plasma and platelets have been extracted. The major importers are SE & SW Thames, NW Thames and Manchester. We estimate that more than 20,000 units are transferred between RTCs within England and Wales (E&W) representing about 1% of total national collection. This represents a range of between 1% - 7% of the "exporting" regions collection and between 1% - 10% of the importing regions requirement. Scotland are providing blood to E & W on roughly the same scale about 20,000

units. All but 5% of "mobile" blood goes to SE & SW and NW Thames RTCs. Scotland provide their blood free. In E & W the exporter is usually reimbursed by the importer for the cost of an empty blood pack and no charge is made for collection or processing.

6.12 Although the problems raised by supply and demand are significant in operational terms to individual regions, in terms of the overall national collection picture they are less so and confirm that a donation target of about 2.2 - 2.3 million will satisfy the national requirement for blood and components at present.

Platelets

6.13 The demand for platelets has been growing considerably faster than that for other blood products. This is due to a combination of better production techniques, which have resulted in a more potent product with a longer shelf life, and new treatment regimes for patients with for example leukemia or those undergoing major surgery. Production of 330,000 units in 1982 had risen to approximately 460,000 units in 1986 equivalent an increase of 9-10% per annum (see Table 16 page 161).

6.14 The majority of clinicians in hospitals and the BTS expect this rate of growth to continue for the foreseeable future which indicates a requirement of 500,000 plus donations in 1987 rising to 550,000 in 1988. Less generally accepted predictions suggest either that maximum demand has now been reached or that demand will reach 700,000 units over the next couple of years.

6.15 Developments in the efficacy of platelets produced, has reduced the standard dose given to patients in one or two regions from 6 units to 4 units. If this trend spreads to other regions, then it will have the effect of enabling the transfusion service to better meet increasing demand for platelets.

6.16 The above factors make predicting future demand for platelets especially problematic. We conclude that for the present it must be assumed that platelet demand will continue to grow at around 10% per annum.

6.17 Increased platelet demand does not directly impact on the number of donations that have to be collected. If there was no requirement to harvest plasma for fractionation then virtually every donation could have the platelets removed since they cease to be functional in stored blood after about 3 days (see paragraph 5.84.2). This gives a theoretical potential of at least 2 million platelet concentrates, well above predicted demand.

6.18 When plasma for fractionation is brought into the equation the picture changes. Every platelet concentrate take up approximately 50mls of plasma. Thus an extra 50,000 platelets (roughly the yearly rate of increase at present) absorbs 2500 litres of plasma and thus reduces that available to be sent to BPL. To compensate for this loss would require centres to collect some 10,000 additional donations (less than 0.5% of current collection) using the SAG(M) system or alternatively to develop platelet pheresis.

6.19 Research is in progress for an optimal additive solution in which to suspend platelets (akin to the SAG(M) system) and this may eliminate the problems in connection with plasma. In general the need for platelets is less a problem of demand than an operational one (see paragraphs 3.5 and 5.94).

Supply

6.20 There are several factors to be considered in relation to the provision of an adequate supply of blood and components required to meet the joint requirements of hospital use and plasma procurement; these are discussed in the following paragraphs.

Regional Self Sufficiency (The London Problem?)

6.21 We have indicated earlier in the report that all but two regions are self sufficient and half are in a position to export on a regular basis. This situation is simply the result of the collection process providing sufficient, or more than is required, to meet hospital demand. Several RHAs as part of the general financial stringency now being applied to and within regions are critically examining the blood collection effort of their RTC. This is being done with a view to aligning the collection efforts more closely to a regional self sufficiency level in terms of satisfying the requirements of hospital need and the plasma target. One region has reduced its collection staff another has restricted collection sessions which are excessively costly in

staff travelling time. It is unlikely that these efforts will totally eliminate surplus in the RTC because of the fluctuating nature of hospital requirements and the inability to make collection patterns totally responsive to them. Others RHAs are content with a surplus situation and did not indicate to us any intention to interfere with the present position.

6.22 It is unlikely therefore that the present regional surpluses amounting to about 20,000 units nationally will disappear completely in the foreseeable future. It is possible however that it might reduce by as much as 50% to about 10,000 units. At present Scotland in providing about 20,000 units to E&W and this is likely to continue in the short term. It is possible however that this assistance may reduce or disappear if Scotland decided to develop a plasmapheresis programme which we understand is a distinct possibility.

6.23 If the recommendation in this report to introduce a management information system is implemented (see para 9.20) it will facilitate better planning and could provide a stimulus to RHAs to critically examine their surplus situation. We conclude therefore that it would be unwise for the BTS in E&W to plan for future demand on the assumption that some 40,000 units will be available at minimal or no cost to supplement deficiences. Several RHAs have indicated that provided they have the capacity they would be prepared to supply blood to other regions on a contract basis. They would be looking to recover the true costs of collection and processing however, rather that the cost of the blood pack as at present. One region indicated that they would seek to include an element of "profit".

6.24 At present only two RTCs - Tooting and Edgware (SE and SW Thames and NW Thames) would be severely affected by a dramatic reduction in the amount of surplus blood available. We estimate that imports represent about 10% and 5% respectively of their RTCs current requirements and consequently any reduction would seriously impair their ability to meet hospital needs. This situation lends itself to several interpretations which are discussed below.

6.25 <u>It is a problem for the 2 RTCs (3 RHAs) to resolve</u>

6.25.1 Edgware requires about 200,000 donations to meet current hospital needs. It collects about 190,000 and imports an additional 10,000. The RTC has the highest blood collection rate in E&W (56 donors bled per 1000 population) and is in fact bleeding at a rate

higher than the recognised saturation point (50 donors bled per 1000 of the population) in the transfusion world. It is unlikely to be a realistic proposition for the RTC to increase the number of donors and it must therefore be considered to be incapable of producing sufficient blood to meet the requirements of the hospitals it serves. The RHA has three options: Firstly reduce demand: since the director estimates that demand is already curtailed to the extent of 10-20,000 units per annum this is unlikely to be a practical proposition. Secondly to attempt to recruit more donors. Even if this is possible it is likely to be at a disproportionate cost. Thirdly to negotiate a contract with another region for a regular supplement and obtain the best possible price.

6.25.2 Tooting RTC - whose bleed figures include the donations collected at the entirely separate Lewisham transfusion centre - serves two regions. At present levels the hospitals in the 2 regions require about 312,000 donation to meet need. The bleed rate (Tooting and Lewisham combined) is 43.5 donors bled per 1000 population. This is marginally higher than the national average (43 per 1,000) but lower than four of the provincial RTCs (see Table 17 page 162). If the bleed rate could be raised to the level achieved by Edgware it would produce about 363,000 donations - considerably in excess of current requirements. If the bleed rate could be raised to 48 per 1,000 (a rate which is being achieved by two provincial RTCs) this would produce sufficient donations to meet current need. There is no inherent reason why the South London population should not donate at broadly the same rate as the population in North London. The RHA could therefore rationalise the current collection and organisational chaos which exists between Tooting and Lewisham; take whatever steps are necessary to increase the donor collection rate to the required level.

6.26 <u>It is a London problem for the 4 London regions to resolve</u>

6.26.1 One of the complications of the London situation which militates against the interpretation suggested in para 6.25 is that

each of the 3 London RTCs (Tooting, Edgware, Brentwood) serves hospitals which are outside its parent RHAs area. The overall requirement for London is

Edgware	190,000 + 10,000 imports
Tooting (and Lewisham)	283,000 + 30,000 imports
Brentwood	139,000
Total	612,000 + 40,000 imports

ie 652,000 donations.

6.26.2 At present the bleed rate for each RTC are Edgware - 56 per 1,000; Tooting - 43.5 per 1,500; Brentwood - 41 per 1,000. To achieve the required number of donations would need a bleed rate at each RTC of 49 per 1,000 which is being achieved by one provincial RTC and being exceeded by Edgware. If only Tooting and Brentwood were to raise their bleed rate to 49 per 1,000 this would provide 675,000 donations for the four regions which is in excess of present needs. If they were to raise their bleed rates to that of Edgeware 743,000 donations would be available to London regions. As suggested at para 6.26 there can be no inherent reason why the populations of various London regions should donate at differing rates. The RHAs would need to either resolve the RTC boundary problems to balance out demand or ignore them and co-operate on supply. Either approach would also require a concerted approach to the question of donor recruitment.

6.26.3 On the basis of our fact finding we have to question whether the necessary will exists on the part of the London RHAs to co-operate to the extent that would be required. An examination of the "London problem" was conducted in late 1985 by the National Director of the Scottish NBTS. Detailed solutions to some of the boundary problems were proposed and despite apparent agreement on all sides little progress on implementation appears to have been made. The problems are compounded by the differing management arrangements. NE and NW Thames RTCs are managed their respective RHAs, Tooting by a joint board of officers from SE and SW Thames RHAs and Lewisham by a DHA. In South London,

despite a committment to an amalgamated BTS for the two regions, Lewisham exists side by side with Tooting without agreed divisions on collection or supply areas. The funding of Tooting is bedevilled by disputes between both RHAs about who is, or should be, funding what, to what extent.

6.27 It is a national problem for the BTS to resolve

6.27.1 Several of the provincal RTCs suggest that they could quite easily raise their level of donation collected with a minimum of extra effort and resource input. Six provincial RTCs estimate that they could produce a total of at least an additional 130,000 donations - the equivalent of a medium sized RTC's annual production.

6.27.2 Although we suggest elsewhere in the report that the available costing figures are somewhat questionable they are at present the only costing information available. If any, or a combination of the six provincial RTCs mentioned above were to collect the additional 40,000 donations required for London, then considerable savings over the cost of collecting them in London could be achieved. For example if the provincial centres with the cheapest collection and processing costs increased their donation levels to the extent to which they suggest is possible then they could provide the additional 40,000 donations for about £365,000 less than it would cost the London Centres to collect them (based on collection and processing costs). Alternatively it would be possible for two provincial centres to produce the additional 40,000 donations for more than £60,000 less even if their RTC overheads are included. This does suggest that a national perspective would produce savings to the public purse. If, for example, all regions were able to achieve the bleed rate of the highest then 2.75 million donations would be available nationally or 2.43 million if the bleed rate of the second highest would be achieved.

6.27.3 There is also an aspect of this problem what has national connotations. The London regions have a disproportionate demand for those products which impact on the ability of an RTC to meet its plasma target and therefore endanger the viability of the national self sufficiency target of 450 tonnes. It is assumed that RTCs can achieve

this target but it has yet to be done. It would therefore be advantageous from a national plasma perspective to make up Londons donations deficit from a source that can ensure the harvesting of a full measure of plasma and not run the risk of its being reduced by the necessity to provide platelets or FFP.

Effective Usage

6.28 It has been suggested to us by some staff working in the BTS and a number of hospital clinicians that there is both waste and inappropriate use of blood and blood products in hospitals. We have found little concrete evidence of the former. The latter is a matter of medical opinion on which we are unqualified to comment. To the extent that either exists they result in RTCs having to supply more blood and products than may actually be required.

6.29 One "measure" of wastage is the blood and product return rates of hospitals. However the term wastage should be used with caution. An out-dated unit is not necessarily a wasted unit. At least part of it's purpose is to be on the shelf available for transfusion and this purpose is served even if it is not used. Return rates are significant in two respects: firstly it can be argued that they represent a level of efficiency in relation to RTC and hospital stock control; secondly in relation to whole blood and clinical FFP, they impact on the plasma harvest. The national average return rate from NHS hospitals is about 8% - covering a range of 3% to 20%. The return rate from non-NHS hospitals, where this information is available, covers a range of 3% to 57% (see Table 18 page 163 for NHS and non-NHS figures). Non-NHS hospitals are discussed at paras 6.45-48 and the following comments are therefore confined to the NHS.

6.30 There appears to be no direct relationship between the return rate and the degree of medical or lay intervention at the issue stage. Some RTCs which impose a relatively high degree of intervention at the issue stage have higher return rates than some who impose a lesser degree of intervention and vice versa. The RTCs which are regular large scale importers of blood, which might imply a more stringent attitude towards effective usage, have low return rates - their average is about 5%. The RTCs which are regular exporters have an average return rate of about 7% yet one of them has the joint lowest return rate in E & W. The regions with the highest return rates are generally those

which are self-sufficient but not regular or large scale exporters. However this group also contains a centre with a return rate of 4%. This suggests that it is possible for RTCs to control the return rates of their hospitals to some extent by influence and/or pressure on hospitals.

6.31 There are factors which justifiably influence the return rate upwards. An RTC may supply outlying blood banks where a stock needs to be maintained for emergency purposes but may rarely be used, or small blood banks where turnover is low resulting in greater potential for outdating. Blood and components have a limited shelf life and it is reasonable therefore to expect a degree of wastage. The majority opinion in the BTS suggests that about 5% is not an unreasonable return rate, however there are proponents of both lesser and higher figures. A range as wide as 3% to 20% does suggest scope for improvements.

6.32 RTCs can to an extent contribute to greater efficiency in this area as witnessed by the varying return rates. Effective stock control systems ensuring that as far as is possible the oldest blood is issued first are necessary. Generally RTCs issue oldest first but stock control is fairly rudimentary. Some, but not all RTCs have established and/or encouraged links between hospitals so that blood which is going to outdate in one hospital is passed on to another which can use it, rather than it being returned to the RTC. Such initiatives, coupled with education of and effective liaison with hospital staff, both medical and non medical, by the RTC are vital in this context and some RTCs must be prepared to adopt a higher profile than previously in this area. We conclude however that the major effort for improvement in return rates has to be made by hospitals - both haematology departments and clinicians - because, in the final analysis, many aspects of this problem are outside the control of the RTC.

6.33 We visited two hospitals in most regions. Many haematologists perceived their role within the hospital to be similar to that of the RTC within the region. They saw a need to liaise with, educate, and if necessary control their customers (the clinicians) in relation to problems, developments etc in the supply and use of blood. As among RTDs, haematologist's attitudes towards this role varied and was to some extent determined by the willingness of their customers to participate.

6.34 Regional return rates disguise individual hospital return rates ranging from nil to more than 20% within the same region. The considerations here are similar to those at RTC level and there must be scope for improvement. Blood ordering patterns vary widely from a standing order arrangement which may or may not be reviewed regularly (or at all) by the haematology department and the RTC, to completely ad hoc arrangements. We saw examples of separate requests for blood being made to an RTC by a single hospital in the course of an afternoon. Each request required separate delivery and we were told in several RTCs that such occurances are frequent. A number of hospitals had inadequate storage facilities to carry an adequate stock and in one hospital this was deliberate policy to avoid the purchase of extra refrigerators. The majority of the hospitals we visited did not operate any real form of stock control and it is therefore not surprising that the dutch auction described in paragraph 6.6 is common-place. These aspects are within the direct control of the hospital blood bank and impact directly on the RTC and the availability of blood and products.

6.35 We also saw mechanisms employed within hospitals which are primarily to control and ease the work flow in the hospital laboratory but which have a spin off effect on the demand made on the RTC blood supply. Examples of these are:

6.35.1 the introduction of computerised blood banking systems has facilitated the initiation of realistic stock control systems in some hospitals. A major thrust behind these systems was to monitor individual clinicians use of blood and blood products as opposed to the number they asked to be cross-matched. Analysis of the results of this monitoring provides a factual basis on which to challenge established ordering practices;

6.35.2 the development of group and screen techniques whereby hospitals do not routinely cross match and put up blood for some surgical procedures. This is intended to reduce the laboratory workload but can indirectly reduce the demand for blood. Group and screen regimes can reduce the amount of blood in the hospital blood bank that is committed to designated patients which in turn allows the blood bank stock as a whole to be reduced. There was wide variation in the hospitals we visited regarding the surgical procedures for which group and screen is considered appropriate and the number of patients that were grouped and screened;

6.35.3 "maximum blood ordering schedules" provide a list of procedures for which an agreed quantity of blood will be cross-matched. Of the hospitals we visited only about half used the system and we also found differences in the number of units suggested for particular operations.

6.36 Although some RTCs have actively sought to encourage hospitals to consider some of these developments there has been no co-ordinated or concerted effort by the BTS to do this. Even if this were to take place the responsibility for implementing and achieving change must lie with the hospitals. We have seen no indication of consideration by either regional or district management of such policy issues in terms of objective consideration of the effect of internal hospital organisation and systems on the requirement for blood supply, particularly from a cost perspective. The introduction of the recommended management information system could provide a stimulus for such consideration as the issues are inextricably linked.

Albumin Usage

6.37 A recurring suggestion throughout the study, particularly from within the BTS, was that there is both profligate and inappropriate use of albumin. The product is fractionated from plasma at BPL and is supplied to hosiptals via RTCs.

6.38 It is difficult precisely to quantify usage because albumin is not only supplied by BPL, but is also purchased commercially by hospitals. In the hospitals we visited it was purchased by either the hospital blood bank, pharmacy or individual departments or a combination of all three. Generally a central record of purchase is not maintained. During the course of our fieldwork we spoke to several Regional Pharmaceutical Officers (RPO) and they did not know the level of commercial purchase that obtained in their regions. In one region the RPO conducted an examination of the situation and discovered that in 1985/86 28% of albumin was purchased commercially. This broadly confirms the estimate provided by BPL which indicates that their 85/86 production represented about 65-70% of current national usage.

6.39 Albumin is used in the treatment of burns and as a plasma expander in a range of other circumstances. In the hospitals we visited we received vastly different views on the clinical necessity for the use of this product. Many doctors took the view that the synthetic substitutes which are available

commercially (at a fraction of the cost of albumin) are adequate in the majority of clinical circumstances. Others supported its use in a range of clinical circumstances and therefore needed to purchase albumin commercially to supplement that supplied by BPL. In some hospitals albumin is regarded as a pharmacy product and the blood bank has no involvement in its issue, use or purchase. One hospital left it's stock on a shelf in the blood bank so that customers could help themselves. Most RTCs have to ration their allocation of albumin to hospitals because demand continually outstrips supply.

6.40 This situation makes the future demand for, or useage of, albumin difficult to predict. Wastage, as opposed to inappropriate use, occurs to an unquantifiable extent due to the fact that BPL issues albumin in two bottle sizes only. Doses of the product that fall outside 100 or 400 mls (or multiples thereof) may lead to some albumin being thrown away since it's sterility is compromised once the bottle is opened. BPL intend to issue a wider range of container sizes to overcome this problem. The extent of inappropriate use is a matter of clinical opinion and therefore an issue we are not qualified to judge.

6.41 Currently an "unofficial" self-sufficiency target of 200 kg of albumin per million population exists by virtue of the fact that this amount will be achieved as a by - product of achieving self-sufficiency in Factor VIII ie the output of plasma required for the Factor VIII self-sufficiency target will also provide the requisite amount of albumin. Since consumption of albumin is at present estimated to be 130 kg per million population in total (ie both BPL and commercially produced product) this target represents, on the face of, an increase is available albumin in excess of 50%. On the other hand Scotland already consumes 240 kg per million population so the E & W self-sufficiency target may be less than is actually needed although Scotland suggest that their treatment regimes may be generous in relation to albumin.

6.42 Whilst predictions on the future level of demand remain problematic what is clear is the need for the BTS and the NHS generally to adopt a positive strategy as regards it's use. Firstly, predicting useage will remain impossible without some monitoring of the amount of albumin purchased and used. Any strategy that includes controlling use will fail without this knowledge. Secondly, RTDs will need to agree a strategy for releasing the extra albumin that becomes available from BPL. In particular, as with Factor VIII, decisions will need to be made as to whether to distribute albumin

according to plasma supplied or need - the two will not necessarily co-incide. Thirdly, the Department will need to decide whether the purchase of commercial albumin should be allowed once E&W are "self sufficient" in albumin.

6.43 In terms of the current target set for albumin self-sufficiency there is no additional impact of plasma collection from the albumin requirement. This would only become a problem if it became apparent that more albumin was required than that which results as a by-product of Factor VIII self-sufficiency.

Shelf Life

6.44 The shelf life of whole blood and red cell components is 5 weeks. All RTCs except East Anglia and the Lancaster centre in North Western Region apply the five week life to their product. The two centres mentioned give a four week life to their product. This is not because their product is less stable than others but simply because the two centres have no difficulty in meeting the needs of their hospitals or collecting blood, indeed both are regular exporters. They have simply never considered it necessary to increase their product shelf life, since to do so would effectively make an additional 20% of these products available which are presumably not needed. In effect therefore the centres could be said to be overcollecting to the extent of 20%. Alternatively, extending the shelf to 5 weeks could provide an additional 25,000 units (60% of the present supplement to London) for the national pool without any increased collection cost.

Non-NHS Hospitals

6.45 The total extent of non-NHS usage cannot be precisely established as not all regions record non-NHS hospital issues separately. This is because four provincial RTCs require that all non-NHS hospital supplies are requisitioned and issued via NHS hospitals who therefore keep the records. Where figures are available they indicate a consumption of about 70,000 units of blood and blood products per annum, 65% of which is dealt with by two RTCs: NW Thames (Edgware) and S E and S W Thames (Tooting). In order to estimate total non-NHS consumption we have assumed that the RTCs who do not record the information supply at the average rate of all other provincial centres (about 2% of donations collected). This indicates an estimated usage of about 80,000 units nationally (about 3% of total national collecton). Edgware and Tooting divert about 10% and 5% respectively of their blood to non-NHS hospitals.

6.46 The rate of growth in demand in non-NHS hospitals at an average of about 20% per year over the last three years is considerably higher than that in the NHS. Opinion suggests that the rate of growth will continue at about this level due to more clinics opening, particularly in the provinces, and existing ones entering the more complex surgical fields such as transplants. Although in terms of total usage of blood and products the demand does not pose a major problem for the BTS nationally it does have a disproportionate effect on Edgware and Tooting which compounds the existing supply problems in those centres.

6.47 The major problem faced by RTCs in relation to non-NHS hospitals is the return rate of unused products. This is around 20% on average compared with 8% in the NHS. Individual regional rates range from less than 10% to more than 50%. Non-NHS hospitals pay a handling charge for every unit they receive. The charge is nationally determined by DHSS and is based upon an assessment of the collection, processing, handling and distribution costs incurred by RTCs. If a product is returned unused and in date to the RTC the charge is refundable. It is therefore quite usual for non-NHS hospitals to retain blood until a short time before the expiry date and then return it to the RTC. Most RTCs will not re-issue any product in case of contamination or deterioration. The handling charge is based only on "front end" costs and the facility for refund takes no account of the cost incurred by the RTC in receiving the unit back or of the fact that the unit is likely to be unusable. In recognition of the problem one centre has an unofficial "no return" policy for in date units, others have ad hoc arrangements whereby if a hospital (NHS or non-NHS) has blood which is going out of date it is encouraged to pass it on to another hospital for use before the expiry date.

6.48 The non-NHS hospital return rate is a source of considerable dissatisfaction in the BTS. The high return rate is due in part to the small size of most non-NHS blood banks. In the hard hit London centres in particular it imposes an administrative burden which is not reflected in the handling charge. It does not seem unreasonable that the handling charge should reflect the returns situation although it should be recognised this is unlikely to be a deterent. Equally RTDs should be encouraged to specifically address the problem of the non-NHS hospitals returns with institutions in their regions.

Plasma Demand

6.49 The UK is committed to a policy of self-sufficiency in blood and blood products. Self-sufficiency in whole blood and red cell products has been attained but some blood products still have to be imported. To achieve total self-sufficiency in England and Wales a new fractionation plant has been built at BPL to fractionate 450 tonnes of plasma per year. In order to ensure that sufficient plasma is available for fractionation each RHA has been allotted a share of the 450 tonne target based on its population. No additional funds were provided to RHA's for this task as it was envisaged that regions would receive in return for their plasma quantities of Factor VIII, albumin and other products sufficient to remove the need to purchase these commercially.

6.50 The imposition of targets received a mixed reception. Some regions were concerned that their demand for Factor VIII was less than would be provided from the quantity of plasma which they were required to supply; others were concerned about the timescale within which they were required to meet their target. Regional response has therefore varied: some regions are ahead of target, some are behind, and several RHAs have set their own timescale which is longer than that originally envisaged centrally. However all are committed to achieving their target. In terms of the effect on BPL this chequered response has not mattered as there has been a delay in the construction and commissioning of the new plant. The delay has however compounded the problems for some RHAs who have found that the additional investment in plasma collection has not produced the expected return from BPL and consequently commercial purchase of Factor VIII etc has had to continue longer than anticipated. Indeed one or two regions informed us during fieldwork that they would consider seeking to have their plasma fractionated commercially if the present level of expenditure continued.

6.51 BPL estimate that they are at present supplying about 25% of the market for Factor VIII and about 65% of the market for albumin. Because of the differing arrangements within regions for commercial purchase of these products it is not possible to establish precise figures but we are aware of one region which purchases 25% of its Factor VIII commercially and another which purchases 75%.

6.52 In order to achieve their alloted target RTCs had broadly 3 options.

6.52.1 to collect more donations - this would entail collecting more blood than is necessary to satisfy hospital demand for red cell products. Consequently once the plasma had been removed the red cells would be surplus;

6.52.2 to increase the percentage of blood collected by the SAG(M) system. This enables more plasma to be harvested from each donation as the residue of red cells are suspended in an additive solution rather than plasma;

6.52.2 to embark on a programme of plasmapheresis.

6.53 Regions have opted for varying combinations of the three options. There was a general view in the medical profession that to collect donations purely to harvest plasma and throw away the red cells would be unethical and could be misunderstood by donors who might be put off donating. Consequently donations have only been increased to an extent sufficient to meet local hospital requirements and, in some cases, to provide a small surplus available for export. To comment on to what extent this attitude is valid is beyond our remit, however we have indicated at the beginning of this chapter that not all red cells are being used. There also appears to be no concrete evidence to support the perceived donor reaction.

6.54 All RTCs, with one exception, have adopted the SAG(M) system. It was anticipated in some quarters that there would be resistance among hospital customers, particularly anaesthetists, to the use of SAG(M) red cells; in addition there is a clinical view that they are not suitable for all transfusion circumstances. Consequently the extent to which SAG(M) red cells could be utilised was widely considered to be no more than about 50% of all whole blood and red cell transfusions. There was a general view therefore that it would be necessary to supplement plasma harvested from donations by whatever method with plasmapheresis to achieve the allotted target.

6.55 The extent to which plasmapheresis has developed in regions has varied widely: in some regions there are large panels of plasmapheresis donors in others progress has been slower. The number of plasmapheresis donations

collected ranges from about 200 to 11,000 per annum, and currently represents about 8% of the plasma sent to BPL for fractionation. About 60% of plasma for fractionation is now derived from SAG(M) donations and about 30% from ordinary donations. Plasma for fractionation is harvested from about 49% of all donations.

6.56 A comparison of several regions illustrates the ways in which different regions have gone about meeting their targets. Each of the regions quoted is ahead of it's target for plasma (at April 1987), four bleed at above the national average rate per head of population, one below. (Figures for all regions are given in Table 19 page 164).

6.56.1 Region A - Harvests plasma from 49% of all donations.
Collects 13% of all donation into SAG(M) packs
Collects 1 plasmapheresis donation for every 12 ordinary donations.

6.56.2 Region B - Harvests plasma from 50% of all donations.
Collects 32% of all donations into SAG(M) packs
Collects 1 plasmapheresis donation for every 53 ordinary donations.

6.56.3 Region C - Harvests plasma from 75% of all donations.
Collects 6% of all donation into SAG(M) packs.
Collects 1 plasmapheresis donation for every 31 ordinary donations.

6.56.4 Region D - Harvests plasma from 75% of all donations.
Collects 58% of all donations into SAG(M) packs.
Collects 1 plasmapheresis donation for every 176 ordinary donations

6.56.5 Region E - Harvests plasma from 47% of all donations
Collects no donations into SAG(M) packs
Collects 1 plasmapheresis donation for every 43 ordinary donations.

6.57 One of the factors in the varied pace of development of plasmapheresis has been the cost of machines and trained staff. Equally significant however has been the widespread acceptence of SAG(M) red cells and the ability and/or willingness of RTCs to divert a greater proportion of donations into this collection system. There was general agreement within the BTS that plasmapheresis would be necessary to supplement the plasma obtained from donations in order to achieve the plasma target nationally. In some regions detailed and costed plans were produced to justify investment in plasmapheresis. In others there does not seem to have been an objective consideration of the options. In several regions plasmapheresis machines are under utilized. Whilst some stand idle others are being used, not as originally planned for the collection of plasma but for the collection of specific plasmas, therapeutic plasma exchange or platelet collection.

6.58 In some regions the investment has been fortuitous as it has enabled increasing platelet demand to be met without drastic impact on the plasma harvest. The development of plasmapheresis is an illustration of a situation where the absence of a management information system and co-ordination led to decisions (or the lack of them) on planning and investment which have since been questioned (or should, in our opinion, have been). Argument continues within the BTS as to whether the SAG(M) system is more expensive that routine donations and whether plasmapheresis is a cheaper method of procuring plasma. The existing costing information (see para 11.35) suggests that SAG(M) plasma is cheaper than ordinary plasma despite the higher cost of the pack and processing. This being so, and clinical considerations being equal, then the proportion of donations collectable via the SAG(M) system is crucial as is the cost of plasmapheresis and the extent to which it is necessary as a supplementary way of collecting plasma.

6.59 We suggest at paragraphs 4.10 and 6.27.2 that it should be possible to increase the donations collected to between 2.4 and 2.8 million per year. If present trends continue hospital usage should be satisfied by 2.2/2.3 million donations per year over the next five years. If 2.9 million donations were collected and 60% bled into the SAG(M) system then this would produce about 454 tonnes of plasma - sufficient for the originally envisaged needs of BPL. This would however also produce a surfeit of red cells which would be surplus to requirements. If 2.3 million donations were collected and 60% bled into

the SAG(M) system this would produce about 372 tonnes of plasma which is insufficient for BPL needs. If the plasma required by BPL turns out to be more than 450 tonnes than in either scenario it will be necessary to increase the plasma harvest.

6.60 The use of plasmapheresis is argued, by its proponents to be the cheapest form of supplement. The cost argument is crucial here and is, to an extent, dependent on the organisational structure which exists. Under the existing organisation the extent of supplementary plasma required will vary from region to region yet each region will be required to invest in plasmapheresis in order to achieve plasma self sufficiency. The cost effectiveness of such a move in terms of each individual region will vary depending on the amount of supplementary plasma required. Within a centrally planned organisation where national, not regional, self sufficiency is the target, it would be possible to plan the plasmapheresis collection programme in such a way as to achieve maximum cost effectiveness. This issue is brought more sharply into focus when, as discussed later, the longer term requirement for plasma for fractionation to produce Factor VIII is uncertain.

6.61 The initial target was 450 tonnes of plasma. It has since become necessary to heat treat Factor VIII which reduces the yield obtained from a given amount of plasma. Therefore the amount of plasma required to achieve self sufficiency (defined as 100 million international units of Factor VIII) may need to be increased unless BPL finds a way to improve the yield of Factor VIII from plasma (as they hope to do). On the other hand England and Wales current consumption of Factor VIII is 80 million units per annum. Present worst case estimates are that the requirement for plasma may increase to 540 tonnes per annum. However given the developments in relation to AIDS and the needs of the Haemophiliac population, the self sufficiency Factor VIII target has, at this stage, to be considered somewhat of a moveable feast.

6.62 Until the new fractionation plant is complete BPL can only process around 150 tonnes of plasma per annum. During this period, as an incentive for regions to produce plasma, a pro-rata distribution of Factor VIII and albumin is in operation. In essence a regions share of BPL's production of these products is determined by the amount of plasma it submits. Those regions who have geared up plasma collection are receiving a larger share of BPL products at present but this will decline relative to the amount of plasma

supplied as other region's collection increases. The underlying drawbacks to the system of regional provision to achieve national self sufficiency is that regions have widely varying populations of Haemophilliacs and thus widely varying requirements for Factor VIII. Also hospitals and regions have widely differing albumin usage (see para 6.38). The position is likely to be reached therefore, either before or when national self sufficiency is achieved, where some regions will have satisfied their regional needs for Factor VIII and Albumin and will have no further incentive to continue to collect plasma beyond that level. In effect a situation which will be reached on plasma supply which is comparable with the situation that obtains today on blood supply. If financial stringencies required RHAs to produce economies then excess plasma supply could be a candidate.

6.63 We conclude therefore that the major factor in the consideration of the plasma target is not intrinsically capacity but the establishment of organisational mechanisms to ensure that:

6.63.1 sufficient plasma in terms of quality and quantity is collected to ensure the viability of national self sufficiency and the investment in BPL;

6.63.2 that the plasma is collected in the most cost effective way consistent with the organisational structure which is in operation.

7. MEDICAL ACTIVITIES AND ASPECTS OF THE BTS

7.1 All of the RTCs are headed by a doctor of consultant grade. Two regions have indicated an interest in appointing managers who are not necessarily medically qualified to head up the RTC. Neither of these regions has suggested that the RTC does not required medical staff on the establishment. All directors indicated that they see their job to be that of manager of the RTC, and that management takes up the majority of their time. All of the directors and most of the regions indicated that they saw advantages in the "manager" of the RTC being medically qualified. Two regions have now formally designated the medical director with the title of "General Manager".

7.2 In addition to the director there are a number of other medical staff on the establishment of each RTC. The number and grades vary but include Consultants, Associate Specialists and Clinical Assistants. There are also sessional medical officers, who may be full time or on sessional contracts, employed to run donor sessions. The activities of these staff are discussed at paragraph 4.6 et seq. Excluding sessional medical officers there are 80 whole time equivalent medical staff working in RTCs. About half of these are consultants (including directors). The number of consultants in individual RTCs, ranges from 2 to 4 and is not related to the size of the RTC or volume of work it deals with. Additionally there is no defined remit for the extent of medical activities within the BTS.

7.3 There is a wide range of medical activities undertaken in RTCs, some of which are determined by the functions and activities of the individual centres:-

7.3.1 the provision of medical advice to hospitals on transfusion problems and enquiries relating to the issue of and requirement for blood and products. This is a function of all RTCs and all consultant staff are involved in the on call arrangements which exist at each RTC to deal with out of hours enquiries. In general medical intervention in the issuing process is minimal. Centres do have arrangements, particularly at times of shortage, whereby particular requests by hospitals have to be cleared with RTC medical personnel;

7.3.2 an extension of the above arrangements is the general liaison which takes place between RTC consultants and customer hospitals. Some centres make each consultant responsible for particular hospitals and they are expected to build up communications and relationships. Other centres have instituted regional "blood user" committees. Some make routine personal visits to hospitals, others rely on correspondence to impart particular information as and when necessary;

7.3.3 the provision of general advice to donors on medical problems and complaints is the responsibility of RTC medical staff. In addition they are responsible for the general medical conditions at donor sessions. Medical policy in relation to which donors will be bled and which donations will be accepted are generally within the terms of a national code of practice but there are variations between and within regions. One region will refuse to bleed a donor who has recently visited a tropical country because of the incidence of malaria. Another region will accept the donation but not use it for transfusion merely harvesting the plasma;

7.3.4 the plasmapheresis and plateletpheresis programmes in each centre are normally overseen by a consultant, usually with the assistance of junior medical colleagues. Apheresis donors are subject to regular medical checks as are donors involved in programmes for the collection of specific antibody plasmas;

7.3.5 quite a large proportion of medical time is devoted to research on the clinical and medical/scientific aspects of blood and products and associated diseases. This may involve collaboration with hospital and/or University departments;

7.3.6 about half of the RTCs are involved in the direct treatment of patients which primarily involves therapeutic plasma exchange. Some centres have plasmapheresis machines dedicated to this purpose others divide the usage of machines between donors and patients. This activity is restricted to those RTCs who are in close proximity to hospitals because of the need for emergency back-up facilities to be available. In two centres the treatment, although carrried out by RTC personnel under the auspices of the RTC, physically takes place in a hospital;

7.3.7 part of the training programme for Senior Registrars in Haematology involves spending several months working in an RTC. Consequently at any given time there is normally at least one Senior Registrar on rotation at each RTC.

7.4 Consultants other than the director may have a range of other responsibilities eg most RTCs have deputy medical directors; sometimes the consultants constitute, or form part of, the management team of the centre; or they provide professional medical advice to the director. They are often the nominal heads of particular laboratories which may involve signing laboratory reports etc, although few have any recognised line management responsibility for these laboratories. Not all consultants are Haematologists and the medical skill mix may indicate the wish of the RTC or it's director to develop the RTC's role in particular areas.

7.5 There are both full time and part-time consultants in the BTS. The part timers have a limited number of sessions at the RTC and usually combine this work with clinical practice in hospitals. One or two full time BTS consultants involved in the treatment of patients also have access to hospital beds. There is some discussion within the BTS as to whether full time or part time appointments are preferable. Those in favour of full time appointments argue broadly that if a doctor has patients they will understandably take precedence over his/her RTC activities which may have to be fitted in "as and when". It is suggested that this is disruptive to the RTC and not condusive to the medical development of the BTS. Those who favour part-time appointments point out that if the BTS is to provide advice to hospitals, and if its advice is to have credibility, then it needs to demonstrate that its doctors have relevant and up to date "hands on" experience of patient care and the problems faced by clinicians.

7.6 There is one other aspect to the role of non director consultants. Because of the concept of clinical freedom a consultant cannot be in a line management relationship the RTD - who is another consultant. Whilst this does not generally impede the running of the BTS several non director consultants in various centres, and one or two directors, have expressed some dissatisfaction with the arrangements. It is obviously in organisational terms not a wholly satisfactorily arrangement and one region is at present

considering amendment to non director consultant contracts to recognise the position of the medical director. Some RTDs have been concerned about their own line management position particularly as the arrangements for general management expand in RHAs and have in some instances removed the RTD from a formal line relationship with the Regional Medical Officer (RMO). Some RTDs have secured a formal line of communication, on professional/clinical freedom grounds, outside whatever line management arrangements that have been applied to them, to either the RMO, RGM or the RHA.

7.7 Consideration of the future organisational structure of the BTS will have to take account of the fact that currently consultant posts in the BTS are a charge on the RHA. In a centralised organisation, if it included consultants who were part-time BTS and part-time hospital, it would be necessary to resolve the arrangements for the funding of such posts.

8. SUPPORT SERVICES

Synopsis

In the support services, as in most other RTC activities, there is a great deal of variety and the considerations for the future are, in organisational terms, similar. These services are perhaps an area in which it would be more difficult to achieve co-ordination without major organisational change because aspects such as computer development and driver conditions are areas in which RHAs might be keen to achieve adherence to region wide policies rather than the relatively narrow confines of the RTC. There is undoubtedly potential for the achivement of savings from a national, co-ordinated approach to considerations of such issues as bulk purchase.

Computers

8.1 All regions use computers to some extent in their RTC. As we have seen in earlier chapters computers are most commonly found in the laboratories and in the donor organisers department but they are also used to assist in stores and budgeting in some centres. Several centres could be described as fully computerised (or very close to that goal), to the extent that computers are involved from donor call up to issue of blood and products. The rest are at various stages of computerisation but all are aiming to be fully computerised eventually.

8.2 There has been little co-operation or co-ordination between RTCs in the introduction of computers. There is a computer users group but this appears to be an informal workshop rather than a policy or decision making body. As a result of the lack of co-ordination the following situations exist:

8.2.1 there is considerable variation in both hardware and software employed in the RTCs. Little of it is compatable which means that the systems cannot be linked if that is ever required. Additionally RTCs cannot share experience or expertise gained in using common equipment;

8.2.2 RTCs have tackled computerisation in different ways, some starting with the donor organisation, others with the laboratories. Function have been computerised differently in different centres;

8.2.3 the different approaches in computerisation mean that the systems in operation have differing capacities to provide management information.

8.3 RTCs have approached computerisation in various ways:

8.3.1 some have designed in house systems using their own resources entirely. One of the most complete and successful systems has been achieved in this manner;

8.3.2 some have utilized RHA expertise in developing systems and this may involve using hardware that is common in the region;

8.3.3 some have gone out to tender to commercial computer firms ("off-the-peg" systems are not available) for their systems.

8.4 To computerise an RTC is an expensive task, probably approaching half a million pounds at todays prices. RTCs have therefore been dependent on the support of RHA in obtaining finance to undertake such a large scale project. This is one of the reasons for the variety in systems. Several RHAs have insisted that RTCs purchase particular hardware or software either because they have obtained favourable terms from manufacturers or to achieve compatability with other systems in the region. Whilst there are some staff savings that result from computerisation many of the advantages are not quantifiable in monetary terms so that RHAs are unlikely to see a financial return on the outlay, at least in the short term. In the financial climate that has prevailed in recent years some RHAs have been reluctant to commit such large sums of capital to their RTC. It is interesting to note however that computerisation has not generally encouraged a re-examination of the staffing levels in RTCs.

8.5 The way that computers have been introduced into RTCs, and the problems that have arisen, demonstrate most clearly the disadvantage of a non-co-ordinated BTS and the waste of resources that can ensue. Three centres are developing in house systems which have involved at least two and up to 5 development staff continously engaged in the task over periods of 3 to 4 years. Essentially they have all been doing the same thing. Much has been made of the differences between RTCs and that therefore they need to be individually

computerised. We do not accept that a common "core" system could not have been developed with, if necessary, modifications for each RTC. It is interesting to note that the RTCs who are not far advanced down the computerisation road are now all contemplating adopting the most successful in-house developed system. Scotland are also proceding with a co-ordinated computerisation programme.

8.6 Computerisation could have offered the opportunity for eliminating operational differences between RTCs. The process involves, inter alia, the examination of how each process is undertaken and, had the task been carried out nationally, could have been an opportunity for the dissemination of good practice and the introduction of uniformity of standards. Instead the diverse approaches taken to the problem have resulted in operational differences being entrenched in different computer systems.

8.7 Three centres have completed computerisation of the major collection and processing tasks and a further four are nearing completion. Three centres have done little in the way of installing integrated computer systems and rely on micros. The remaining six are at various stages of the task. The actual cash investment is difficult to establish since manpower costs of developing and installing equipment are generally not identified. In terms of hard and software, costs of between £250,000 and £350,000 have been quoted by RTCs that have integrated systems. As an indication of the present cost of starting from scratch one RTC that has yet to computerise has earmarked £500,000 to do so. Clearly in the short term too much money has been committed to existing systems to abandon these and adopt a national approach. It is encouraging that at this late stage at least some RTCs will share common systems and perhaps these may eventually lead to national standards. Computers develop quickly and it will not be long before those who computerised first will be looking to replace or update their systems. If resources are not to be wasted a second time a more co-ordinated approach should be considered at an early stage.

8.8 In terms of management of RTCs computerisation offers the opportunity to produce effective management information systems and for a more sophisticated approach to such activities as donor call up and blood bank control. They also enhance safety and can lead to staff savings in some

areas. As indicated earlier it may be that the full advantages offered by computerisation can only be achieved via a centrally funded and managed BTS since availability of finance and positive management control are needed for its introduction.

Blood Banking, Orders and Issues

8.9 Oversight of the blood bank and issues is generally the responsibility of one of the laboratory technicians, often either the head of the laboratories or the head of the blood products laboratory. The actual job of taking orders for blood and blood products and issuing them plus control and rotation of stock is variously carried out by clerical staff, junior laboratory staff or ancillary grades such as orderlies, porters, drivers or telephonists.

8.10 All centres have regular rounds to their client hospitals. Most expect the hospital to place it's order the day before for delivery the following morning, or perhaps in the morning for delivery in the afternoon. However in one region the delivery van holds a stock of blood from which each hospital on the round takes what they require. Centres operating the former system produce a delivery note and make up the order prior to despatch. In the region operating the latter system the driver has to make out a delivery note at the time of delivery. The majority of RTCs use a microcomputer to produce the delivery note and many take advantage of light pen systems to control issue. It is of course extremely important that the destination of each unit of blood or product is recorded in case any information comes to light about the donor that requires the unit to be recalled, if it has not been transfused, or the patient to be traced if it has.

8.11 Apart from regular rounds the orders and issues department will be dealing with "ad hoc" orders that hospitals have to make when they find they do not have a product they require at short notice. Authority to make issues outside normal deliveries may be delegated to the staff in the issues department or they may be required to refer to scientific or medical staff. During normal working hours this does not normally require special arrangements but, at night the RTC may be looked after by ancillary staff. In these circumstances they have instructions on what they can issue on their own authority and in what circumstances they must refer to the on call doctor or scientist. We have discussed elsewhere the effect medical/scientific intervention has on demand (see para 9).

8.12 Stock control in most RTCs is fairly rudimentary. In most a "state of the bank" is compiled once a day. This is either done manually (by counting) or from microcomputer records. Only the fully computerised centres have real time stock control ie state of the bank available at any time. The state of the bank is usually reported to the director and heads of departments. Stock control is important in optimizing the availability of the various products made at RTCs, especially those with a short shelf-life. However, it is of limited value in dictating the amount of actual blood in the bank because of the relatively long lead time between recognising a shortage or surfeit and affecting the collection programme. Only if the bank was to be consistently short or overstocked over a period of a month or more is it likely that the situation would be controlled via the collection programme.

8.13 The response to a shortage in the bank is generally to control issues more critically whereas a surfeit will result in hospitals getting what they ask for or indeed being offered extra. There is a "trade" between regions, in red cells, but this is extremely ad hoc. In theory the Cardiff RTC acts as a clearing house for shortages/surpluses but this has never worked effectively. Most RTCs (and their directors) have associations with particular RTCs and use these links to obtain extra supplies.

8.14 Overall we would expect that computerisation of blood banking ought to facilitate better stock control and this in turn should allow RTCs to better utilise the blood they collect. The improvements that can be made in this area are probably marginal. Given the problems indicated in the supply and demand chapter the area that requires most attention is liaison between RTCs over their stocks so that surpluses/deficiences are notified through the service more quickly.

Stores and Equipment

8.15 The arrangements for the purchase and storage of supplies varies from region to region. Regional supplies arrangements are in many cases in a state of flux as some centralise stores within the RHA. Where this has occured RTCs may be included in the arrangements whilst others are left to fend for themselves. RTCs are normally able to take advantage of RHA contracts (and thus the discount available to RHAs for volume purchase) when dealing with the purchase of items that are commonly used throughout the health service but

there are some pieces of equipment and disposables used soley, or mostly, by RTCs. The volumes of such items purchased by one region may not attract the sort of discount that would be available if the total requirement for the BTS was purchased centrally.

8.16 In the area of equipment the chief items that might benefit from central purchase are blood grouping machines, computers and centrifuges. Central maintenance contracts may also be of benefit. It is difficult to quantify at present what, if any, financial savings would accrue but it should be noted from an organisational point of view that any benefits would be more easily achieved under a centrally financed BTS that under the present regional arrangements. The latter need not be a barrier if individual RTCs could agree that one of them should act for the rest and the necessary financial arrangements agreed by regions.

8.17 Disposables, primarily blood bags and collecting equipment, account for a substantial proportion of each RTCs budget. Most agree that the central purchase of the packs etc could give larger discount than is obtained by individual RTCs. One manufacturer has tried to secure a service wide contract but a number of factors have prevented this being taken up so far. Centres cannot agree on which packs are the best and, as we indicate in paragraph 5.89 a wide variety of configurations are in use. Also there are fears that to give one manufacturer a monopoly of supply would not be in the best interest of the service and would perhaps lead to a loss of any discounts obtained initially. It has been estimated that a service wide contract would save the BTS some £350,000 per year. We have not seen the calculation producing this figure and cannot comment on its accuracy. It seems likely however that savings would accrue from a national contract for pack purchase with a number of manufacturers to avoid the fears mentioned about a monopoly supplier situation.

8.18 One division of the BTS has attempted to negotiate a contract for the RTCs it encompasses. This has been of limited success and, as with equipment, suggests that the benefits of central purchase of blood packs may only be achieved under a centrally managed BTS.

Transport

8.19 Each RTC has a transport department and fleet of vehicles. In total the BTS in England and Wales use just over 400 vehicles of various types. In the year ended 31.3.86 these vehicles covered nearly five million miles between them.

8.20 Transport is required for a variety of reasons in the BTS the chief of which are:

8.20.1 taking staff and equipment to and from donation sessions;

8.20.2 transporting blood and blood products from donation sessions to the RTC and from the RTC to hospitals;

8.20.3 delivering plasma to BPL;

8.20.4 ferrying donors to and from donation sessions;

8.20.5 publicity and recruitment work; and

8.20.6 general administrative and service purposes such as waste disposal, stores collection etc.

8.21 In addition to their own vehicles RTCs may use taxi or rail services in some instances for blood delivery. Taxis are also used to transport donors on occasions. In some centres the transport department controls all transport services including taxi and rail services. In others the latter are dealt with by administrative staff or blood issues staff.

8.22 There is no common policy on vehicle design or purchase: there is even no common livery for NBTS vehicles. In most centres the following types of vehicles will be found:

8.22.1 equipment lorries - these are used to transport the equipment necessary for donation sessions to and from session venues. Vehicles used for this purpose include Leyland Terriers (7.5 ton); Ford D Series trucks and Dodge trucks. Generally the carriage area has to be fitted out specially to store the session equipment. Refrigeration units or cold boxes for the storage of blood are also fitted. Some RTCs reuse the carriage box, merely replacing the chassis as necessary;

8.22.2 minibuses - used for ferrying staff and donors to and from sessions. Usually standard model Transits with 12 or 15 seats but a few Mercedes and Talbots are also used;

8.22.3 delivery vans - used for deliveries to and from hospitals. Again the most commonly used van is a Ford Transit. Others used include Sherpas, Dodges and Bedfords. Some are fitted with refrigeration units or cold boxes;

8.22.4 cars and estates - these are used for a variety of purposes including: ferrying of donors; delivery of small amounts of blood; emergency ("blue light") deliveries; use by staff on official visits. The variation in type of car used for this purpose is considerable but Ford Sierra and Vauxhall Astra estates are quite popular. Estates of that general type and size (1.8 to 2 litre engine) are favoured for their load and passenger carrying capacity.

8.23 The above vehicles are the four main types in use. However three RTCs use a combined equipment and personnel carrier for donation sessions and these are custom built vehicles.

8.24 Apart from the vehicles listed above a range of other types are used by some centres:

8.24.1 bloodmobile - this is a mobile donation centre. Three centres have these: two are trailers pulled by a tractor unit, the other is a converted coach;

8.24.2 landrovers - 7 centres have these. Generally used as bad weather/recovery vehicles;

8.24.3 publicity vans or trailers - 8 centres use these. Most have trailers or caravans but 3 have vans;

8.24.4 one centre has a mobile manual plasmapheresis unit which is now little used.

8.25 Finally, all RTCs require some method of transporting their plasma to Elstree. This needs to be a vehicle or trailer capable of sustaining a temperature of minus 40°C ideally. However, not all centres have a vehicle capable of this. Edgeware, because they are only 15 minutes or so away from Elstree, use cold boxes and eutectic plates capable of sustaining temperatures of 4° - 6°C only. At the other extreme three centres have vans fitted with liquid nitrogen refrigeration units capable of sustaining minus 40°C. A further three centres use specially built freezer trailers.

8.26 BPL have been concerned that the quality of plasma they receive may be affected by the storage conditions it is kept under during transportation. A joint RTC/BPL committee was formed to look at this problem and recommended that freezer trailers be used by all centres. The RTDs agreed to this is principle and prototype trailers have been built. However, as yet a final design has not been settled on. The suggestion is that BPL commission and purchase the trailers and then lease them to the RTCs. The fleet would be large enough so that RTCs could deliver a full trailer to BPL and pick up an empty one (or one loaded with BPL products for the RTC). This would reduce turn around time. Equally the trailers could be used as extra storage capacity at the RTC since they would plug into the electric supply when not being towed. This would also allow BPL to unload the trailer at their own convenience. Perhaps yet another illustration of the lack of co-ordination which exists is that having reached "agreement" on the trailer one RTC spent £20,000 on a refrigerated truck to ferry its plasma to Elstree.

8.27 Apart from the different types of vehicles and mix of manufacturers used by the RTCs other differences exist. Some use all petrol vehicles, others all diesel and yet others a mixture. Some buy fuel in bulk and have pumps on site, some get it on DHA/RHA contracts, others buy it commercially on locally negotiated contracts. Servicing and maintenance may be carried out in house, contracted out to DHA/RHA transport depots (eg ambulance depot) or contracted out to commercial firms. Buying and disposal of vehicles also varies as do replacement policies. Several centres provide a maintenance or service for DHA or RHA vehicles: this may or may not be on a re-charge basis.

8.28 It seems on balance that it would be worth examining in detail the possibility of producing a national specification for some, if not all the BTS vehicles. Certainly those which have to be "customised" for BTS use (for example the equipment vehicles) may be obtained most cheaply if ordered in

volume from one supplier. Differences in equipment used may give rise to design difficulties. However this equipment could also be standardized in time. The experience of the freezer trailer committee indicates that it is possible for centres to agree on standard designs but it also indicates where difficulties may arise in the implementation of agreement under the existing organisational structure.

8.29 A number of people we spoke to drew our attention to the fact that different vehicle liveries are used by different Regions. If the BTS wishes to present itself as a national organisation there would be merit in a uniform livery. If, alternatively, the service wants to emphasize it's regional nature, then individual liveries could be retained. It was apparently agreed that the BTS should move towards a common livery of white and red however some RTCs have since decided not to go along with this.

8.30 Management of transport is vested in either a senior driver or, more frequently, a Transport Manager who is on the admin and clerical staffing structure. The Transport Manager will generally have responsibility for all aspects of RTC transport and reports to the senior administrative Officer, or even in some cases, to the director. Senior drivers may have more restricted duties but again some are effectively doing the same job as a Transport Manager.

8.31 The types of vehicle to be purchased, particularly equipment vans, will often be decided in conjunction with the RTD/scientific staff. The Transport Manager will then be responsible for obtaining the specified vehicle. This may be through local tendering or through DHA/RHA tendering arrangements. The latter may result in a different vehicle to that ordered being obtained. Replacement policy is theoretically in line with Departmental Transport guidelines but financial constraints imposed by some RHAs have meant that in practice there is variation from centre to centre.

8.32 There needs to be considerable liaison between the transport department and blood issues over delivery. The number of deliveries a hospital has per week is generally determined by the medical/scientific staff. The Transport Manager puts this requirement into a workable, economic round. "Ad hoc" deliveries, those required outside a normal round, form a high percentage, in

some centres as much as 50%, of all deliveries. In some RTCs the transport department decides whether to use BTS drivers, taxis or trains. In others this is done by the blood bank. One RTC has recently introduced a nominal charge for ad hoc deliveries in an attempt to reduce them but as yet it is too early to say if this has been successful.

Drivers

8.33 Although most drivers are graded ASC6 RTCs have different expectation in their deployment. As we indicate at paragraphs 4.5.1 and 4.5.2 RTCs have differing views on a drivers function at blood collection sesions. Additionally some RTCs require some or all drivers to hold HGV licenses. At some RTCs drivers also provide the night staff to cover the RTC during silent hours. Whilst on night duty they may be expected to take orders for blood and arrange their dispatch. They may also be responsible for the security of the RTC at night. Regions have varying agreements with the trades unions regarding the terms and conditions of drivers.

9. MANAGEMENT AND MANAGEMENT INFORMATION

Synopsis

We conclude that the major management problem confronting the BTS is the absence of reliable and uniform management information. In our view resolution of this problem is of paramount importance and is the key to the effective management of the BTS in future regardless of what organisational structure one implements. To this end we recommend as a matter of priority the establishment of a national, uniform system of management information funded centrally.

9.1 In most regions the RHA style of management has had little impact on how the RTC is run. The application of general management to RTCs has received little attention until recently. There are signs now that some regions are reviewing their role in relation to the management of their RTC and, in some cases, the internal management of the RTC itself. In other regions, designating the RTD as the budget holder for the RTC is about the limit of the change introduced as a result of general management.

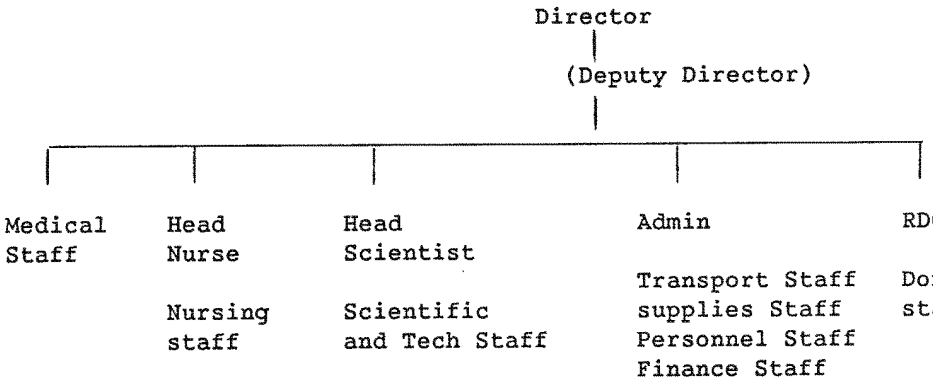
9.2 It is generally agreed that the BTS today is a far more complex organisation than that of even 10 years ago. All the directors spend the majority of their time managing the RTC (a number expressed regret that time formerly available to pursue laboratory or clinical interests had been eroded by the demands of their role as managers). With one or two exceptions the directors have had no management training to help them meet the changing demands of their job.

9.3 Formerly the most important administrative post in an RTC was the RDO whose responsibility is to recruit donors and arrange donor sessions. As the complexity of the serivce has increased the importance of the administration post has also increased so that now, in most centres, the administrator is graded higher than the RDO and in some cases is now managerially responsible for him/her.

9.4 The NBTS appears to have had some difficulty in attracting high calibre administrative/management staff. Administration posts in the NBTS are somewhat out of the mainstream career path for NHS administrators. Additionally the posts have not generally been very highly graded and the

tendency for much of the management responsibility to be concentrated in the directors hands might have made the job unattractive to managers looking for a post with a degree of autonomy and responsibility. Over a period of time the role of both the medical director and the administrator has changed as the need for expert management has increased with the increasing complexity of the BTS operation and the increasing emphasis on financial management. One or two regions have recently appointed relatively senior grade administrators whose role is envisaged as being higher profile than previously, particularly on the financial front. The grades of RTC administrators range from scale 9 to 23.

9.5 The majority of RTCs have a similar organisational structures broadly based on professional groupings. A typical example would be:-



Deputy director's, where they exist, are usually consultants. Where the above structure exists it is also quite common for there to be a management team, or group, that meets at regular intervals to discuss general policy. In some centres they are actually decision making bodies, in others they act more as a sounding board or advisory body for the director.

9.6 The difference in management styles and arrangements is mirrored in the differing arrangements for financial management within the RTCs. In most centres the director is the budget holder and several directors to all intents and purposes keep financial control to themselves (although they may be assisted in dealing with the minutiae by the Administrator). In other centres there are systems of sub-budgets at departmental head level and sometimes down to operational level. These arrangements may sometimes be little more than cosmetic eg an individual may have the facility to purchase minor supply items or alternatively they are more real and accountability processes exist. In

all instances of delegated budgets manpower is excluded. Several centres have developed more radical systems. In two centres full financial control is exercised by a highly graded administrator/finance officer. Another RTC is introducing a system of delegated budgets with inbuilt accountability processes under the guidance of trained personnel. In two other centres the director is the budget holder but all financial matters are the responsibility of, and financial expertise provided by, finance personnel at the appropriate Health Authority.

9.7 In all regions systems exist whereby the RTC receives regular budget statements from the RHA. The extent to which these are used to monitor budget performance and take action on over/under spending is limited. This tends generally to be a formal process with little meaningful questioning or review. In turn it appears not to trigger much response in the RTC. The major problem confronting management, and that which impedes effective financial management; is the absence of reliable information to provide a basis for assessment of performance and formal accountability. Budgets may be restricted, or savings achieved, on the basis of cost improvement programmes or competing priorities but this is in the context of the regional financial situation not RTC performance. This is not to suggest that such "cost control" is invalid but it behoves the system to be aware of the performance and service impact of such controls.

9.8 The absence of information manifests itself in the fact that although there is an awareness of the cost of the RTC in financial terms there is at RHA level little understanding of why it costs what it does, or a statement of what the policy parameters are in relation to that cost. Furthermore there is little formal recognition that developments within a region can impact on the resource requirement for the RTC. Several centres experience difficulty in convincing their authority of the impact of such developments for them and the consequent resource implication.

Existing information

9.9 Form NBTS 47 is compiled quarterly in RTCs and submitted via RHAs to DHSS. It is a record of some of the activities in the BTS for example: total donors bled, product issues and returns, plasmapheresis donations and FFP sent to BPL. It does not cover all BTS activity eg it does not give information about the number of donation sessions, it does not detail all therapeutic

products issued, contains no reference to diagnostic products or laboratory activity generally and provides no information on staff resources. No individual in DHSS has any responsibility for examining the information critically or initiating action or enquiries in relation to it. It tends to be collated late - in April '87 we were only able to obtain details of the first quarter in 1986 from DHSS. During our factfinding it was not always apparent that the RHA were completely aware of the existence or content of these statistics. The statistics are merely a record, and a very incomplete record at that, of some aspects of BTS activity. It is however the only information that we have discovered which draws together BTS activity on a national basis.

9.10 Cost form 60 - this is a fairly recent development and its purpose is primarily to provide the basis for the calculation of a "handling charge" for the blood and products supplied to the public sector. The form is compiled by RHA treasurers departments on the basis of information supplied by RTCs Simplistically the overall budget of the RTC is allocated (with certain weightings), after excluding that element which is devoted to non core functions such as ante-natal testing, to the various blood components produced by the RTC to give a cost per product.

9.11 The system is not designed to produce an accurate or actual cost per product. The instructions regarding the compilation of the information allow some latitude as to how the calculation may be made and what factors are included and consequently we have found different regions using different bases for the calculation. This is perhaps best illustrated in the differing figures produced to represent "technical services" ie that element of the budget relating to non core functions. The proportion of budget identified ranges from 4% to 42% with centres providing a broadly similar service showing vastly different proportions. In some regions which fund the RTC to centrally purchase additional Factor VIII this sum is included in technical services; in others it is not but is rather distributed throughout the budget inflating the cost of other products. Obviously the figures produced are therefore distorted and this distortion is not uniform which creates anomalies in the information produced. Examples of the variation in costs produced are: (see Table 8 page 159 for figures for all regions)

9.11.1 total cost per donation ranges from £25.55-£38.58 - 33% difference;

9.11.2 collection cost per donation ranges from £11.68-£20.29 - 78% difference;

9.11.3 grouping cost per donation ranges from £1.13-£3.62 - 220% difference;

9.11.4 products cost per donation ranges from £1.27-£4.84 - 280% difference;

9.11.5 distribution cost per donation ranges from £0.58p-£2.09 - 260% difference.

9.12 The system is not designed for "monitoring" (in performance terms) purposes and, as far as we can gather, for critical analysis by the DHSS. It has however been quoted to us during fieldwork by various centres to support their contention that they are the cheapest, most efficient etc. The information it produces may be perfectly adequate to the purpose for which the system was designed however it is clearly not adequate for any MIS purpose. It is however the only national costing information which is available, indeed we refer to it throughout this report, and the vast ranges of difference it produces could at least provide a basis for some tentative questioning of RTC performance. We have not discovered any attempt to do this at regional or national level.

9.13 All other BTS information is collected within individual centres and, as far as we can gather, not disseminated outside the boundaries of the region. The statistical information maintained by RTCs varies and ranges from the relatively simple to the relatively sophisticated. In some centres statistics are maintained by individual departments in isolation, in others they form part of a package. We sought to obtain some basic statistical information from centres during the study and were surprised by the extent to which some centres had difficulty in providing, or were unable to provide, some items of information such as return rates on some products, quantities of some products made, number of usable donations obtained from sessions or donors transferred in and out of region.

9.14 Broadly the statistical information available in the BTS is as follows:

9.14.1 number of donors, new donors gained, donors lost;
9.14.2 number of donors invited to session, numbers attending;
9.14.3 number of sessions;
9.14.4 number of donors rejected at sessions (and reasons);
9.14.5 number of donations obtained at sessions and via plasmpheresis;
9.14.6 number of screening tests conducted, result of tests;
9.14.7 number of bacteriological tests conducted, results;
9.14.8 number of samples analysed ie special reference, ante natal, tissue typing etc, results of analysis;
9.14.9 number and type of therapeutic products made;
9.14.10 number and type of therapeutic products issued;
9.14.11 number and type of therapeutic products returned;
9.14.12 number of diagnostic products used or made;
9.14.13 plasma sent to BPL (routine and specific);
9.14.14 vehicle mileage, fuel consumption etc;
9.14.15 number and grades of staff employed.

Some RTCs produce annual reports for their RHAs or for internal consumption containing a range of statistical information.

<u>The requirements of an information system</u>

9.15 Whilst there is a great deal of information available within the BTS it is at present little more than statistical records. It is seldom manipulated or used to define, assess or monitor performance. There is no costing system, beyond that outlined at paragraph 9.10, which produces a real cost of particular activities or products in terms of the actual resource - manpower and non-manpower - which has been input. Collection and production is not generally monitored in terms of targets and actual achievements but rather by "have we met demand?".

9.16 Each centre assesses the number of donations it needs at the start of each year. This is normally based on historical data coupled with predicted developments. Few regions have planning mechanisms to enable RTCs to be made aware of regional and district developments which may effect the demand for blood and products. The system relies, to a great extent, on the directors keeping in touch with professional colleague or perhaps perusing regional and district strategic planning documents.

9.17 Even if an RHA is in possession of the full range of it's RTC's management information it can make limited use of it. For example the RHA is unable to monitor performance because of the absence of benchmarks by which judge: it may know that 100 donations are collected on the average session by 11 staff, or that 10 staff in the ante natal laboratory deal with 80,000 samples annually; but providing that this performance remains fairly constant it has no basis to question it. Furthermore it will not know that the neighbouring region is achieving 140 donations and 140,000 samples with the same number of staff. We should add that generally we have not seen indications of such critical analysis of existing data by regional management.

9.18 The lack of management information, particularly costing information, is in our view one of the major reasons for the varying levels and pace of development in the BTS. Whilst some efforts have been made to produce costed cases for certain developments, the fact that information has not been collected systematically has often meant that special exercises had to be mounted in order to gather the relevant data and that that data, and the conclusions based thereon have been questioned on the basis of accuracy and validity. The fact that there is very little information collected in a common manner (basically only that returned to the Department on form NBTS 47) has meant that inter-regional comparison of data or performance has been of dubious value. Where comparisons have been made it has been difficult to sustain criticism of poor performance against the argument that the data on which such criticism is made is not strictly comparable. Issues have not been resolved and RTCs and RHAs have therefore gone their own ways based on their own convictions.

9.19 The lack of formal accountability, both within RTCs and between them and RHAs, has meant that there has been little demand for management information. In the post-Griffiths NHS this situation is changing. Some RHAs are becoming more interested in their RTC and are starting to ask questions about performance, efficiency, value for money etc. To answer these questions and meet criticisms directors will require more detailed performance information. More importantly, this information is needed to promote better planning and financial management. Regardless of it's organisational structure the BTS, or particular regions, may soon be faced with making

decisions about how to approach the problem of matching demand with supply. As we indicate in paragraph 6.27 these are, at root, decisions that will turn on cost factors. Unless these fundamental operational costs are known for all regions then the decisions cannot be soundly based and will result in an unnecessary waste of resources.

The proposed system

9.20 We therefore recommend that priority be given to developing a common management information and costing system for the BTS. It should be clear that this will not of itself solve the problems within the BTS that we have identified. The object is that it should provide the information which is necessary in order that those problems can be addressed. It will be important that the systems are developed in co-operation with staff who will have to maintain and use them. It will also be essential to train managers in the interpretation and use of the information generated.

9.21 The system when developed should be capable of use for the following purposes:

9.21.1 forecasting demand - not only for blood products but also other services provided by the RTC. In essence this will mean using historical data much as now. As we indicate in chapter 6 the likelihood is that growth will not exceed recent historical patterns and may possibly decline. It is likely therefore that simple extrapolation will be adequate without the need for such sophisticated techniques as regression analysis. It would be possible to produce say five year forecasts annually. This would need to be supplemented by a formal system of advance planning so that regions and districts ensured that all developments which affect the demand for blood and products were notified to the RTC. This would then facilitate the development of production scheduling systems;

9.21.2 target setting and performance assessment - the system should allow managers to be set, and agree, realistic targets for performance, and for continuous assessment of performance against targets. This would require the establishment of "key result areas" both for the RTC in general and each department and laboratory in particular. Objectives would have to address the questions of quantity, quality and accuracy;

9.21.3 assessment of staffing requirements and workload measurement - measures should be developed to translate increases or decreases of workload into staffing requirements. In the short term this would mean comparing performance/production in relation to existing staff complements and by definition it will assume that existing staffing levels are correct. In the longer term a system of workload measurement would enable a more objective considerations of staffing levels in relation to workload;

9.21.4 production of costing information - unit costs should be produced for all products made (therapeutic and diagnostic), tests, blood collection and distribution etc. The costing system would in effect be a result of the previous three aspects discussed in the preceding sub-paragraphs. It would be based on a calculation of the actual manpower and non manpower resources involved in the process. It would, in due course, provide the basis for a charging system if this were considered necessary;

9.21.5 stock control - including monitoring of issue patterns, return rates etc so that these can be fed into production planning, and the identification of long term trends;

9.21.6 produce performance information that can be the basis of meaningful inter-regional comparison of performance.

9.22 Experience of the revised financial costing package has shown that operational variety between RTCs can lead to widely differing interpretations of instructions. The most important aspect of this system is that it should be uniformly applied to each RTC so that it can be the basis of meaningful inter-regional comparison. For this reason we do not think it practical that a package of instructions be developed and then each RTC left to implement the system as they see fit. As we have indicated throughout this report the extent of operational variance between the RTCs is considerable. It is therefore necessary that the information system expresses the variance in common terms of productivity, quality and cost; indicates whether the variance is of any significance and thus provides the basis for management action. This requirement applies equally to the RTD who needs to hold his managers accountable for their performance, to RHAs which need to hold RTDs accountable and to DHSS which needs to hold RHAs accountable.

9.23 The construction of the package should be overseen by a representative steering committee of senior officers from RTCs, RHAs and DHSS to ensure that the information needs of each level of management are encompassed. In order to ensure national compliance the exercise should, in our view, be a Departmental initiative.

9.24 We would not wish to understate the scale of the task. However sufficient raw data is available within the BTS at present to enable crude comparisons of performance to be made, for example the ratio of collection staff to donations collected. Such comparisons, whilst not providing answers, do provide the basis for questioning performance: all that is necessary is to ensure that the information is collated and that management is required to take account of it. The operational variances between centres will mean that such comparisons will be the subject of superficial explanations or be dismissed out of hand. In our view information presently available can only be of value in the interim until a carefully designed and planned system can be developed.

9.25 To construct the package will require two areas of expertise: in depth knowledge of the workings of the BTS and expertise in information systems design. The former is available within the BTS and the steering committee could decide to ask the existing BTS specialist committees (para 2.2) to produce key result areas, performance indicators etc for their aspects of RTC work. These would be in line with the broad outline of the system detailed at para 9.21. Work on information systems and workload measurements is being done at the moment in some RTCs. Bristol are examining the Canadian Unit system, Birmingham are working on the College of American Pathologists Work Measurement system and performance and costing systems. Trent are examining production scheduling methods. Therefore expertise on this aspect is also available within the BTS. It is likely that this will need to be supplemented and further expertise could be obtained from either DHSS or RHA management consultancy or commercial consultancy firms. The information systems experts would work in tandem with the professional committees and the steering committee to produce the package. The cost of buying in the expertise will depend on what is available within the BTS but is unlikely to exceed £100,000 assuming that DHSS or RHA management consultancy resources can be utilised.

9.26 The system should, in our view, be introduced at the earliest opportunity and from this viewpoint there may be advantages in implementing the crude package mentioned in paragraph 9.24 in the short term whilst

development work on the main package is carried out. There seems no reason why the crude package could not be in place within about 12 months of the decision to implement it. The full package will take some time to design and develop, we would estimate about two years from the commencement of work on it.

9.27 The information system is not, in our view, dependent on any particular organisational option, the only difference would be the levels to which the information was promulgated. For example if the BTS remains under regional management we would envisage the package as being of relevance at RTC, RHA (or DHA) and DHSS levels. The package would need to be collated centrally, presumably by DHSS, and it would be necessary to ensure that the information was provided and circulated promptly. If the BTS was centrally organised then the information would be likely to be only of relevance to RTCs, the central authority and DHSS. It is unlikely that the content of the package would be significantly different under either option. In the longer term, particularly if the BTS is to remain a regionally managed service, it will be necessary for the BTS MIS to fit into the general NHS MIS. The parameters which we have identified are in line with the Korner PI approach and indeed include those areas which Korner envisages it necessary to monitor. In view of this it is not necessary for the BTS to await the advent of the full Korner package - indeed it would be counter productive to do so.

9.28 Depending on what organisational decisions are taken in relation to the BTS, and the speed of their implementation, the information system might require some additional staffing resource to monitor its introduction and deal with any problems arising. The cost of this resource is unlikely to exceed £50,000. The package will need to accommodate existing and planned computer installations and manual systems. Although the ultimate system would be more easily accommodated within a computer system it is important to note that it is not, in essence complex once its parameters have been designed and it could be contained within a manual system. In our view the package is crucial to the viability of all of the organisational options. It should therefore be centrally funded to ensure universal application and a common starting date.

10. CENTRAL BLOOD LABORATORIES AUTHORITY (CBLA)

Synopsis

We conclude that communication and co-ordination between RTCs and CBLA need to be improved if the collection and fractionation of plasma is to be achieved with maximum economy and efficiency.

Functions and Objectives

10.1 The CBLA is a Special Health Authority (SHA) which was set up in 1982 to manage:

10.1.1 the Blood Products Laboratory (BPL) at Elstree;

10.1.2 the Plasma Fractionation Laboratory (PFL) which is part of BPL but sited at the Churchill Hospital Oxford; and

10.1.3 the Blood Group Reference Laboratory (BGRL) which is sited within the Radcliffe Infirmary at Oxford.

10.2 The statutory objectives of the CBLA are:-

10.2.1 the provision of laboratories for the manufacture of blood products and other purposes;

10.2.2 the preparation of plasma fractions for therapeutic, diagnostic and other purposes;

10.2.3 research and development in plasma protien fractionation and for other purposes;

10.2.4 the manufacture of blood grouping reagents and other related reagents.

10.3 The production of therapeutic products is concentrated at Elstree where a new, purpose built fractionation plant was opened recently. The fractionation laboratory at Oxford acts mainly as a pilot processing facility for the development of new techniques and products. Reagent production is carried out at the BGRL laboratory and used to be under the management of the

director of that unit. However, as part of a recent reorganisation of BPL a new branch, BPL Diagnostics, was created which brought the management of the reagent operation under the director of BPL. It is hoped eventually to move both the pilot processing facility and reagent production to the Elstree site.

10.4 The future location of BGRL is uncertain. The present laboratories have to be vacated and BGRL is expected to move to Bristol. The date of this move has yet to be finalised.

Interaction with RTCs

10.5 The management arrangements are described at paragraphs 2.8 and 2.9. This report does not examine the day to day activities of CBLA and it's constituent laboratories except in so far as these impact on RTCs or vice versa.

10.6 The most important area of interaction between CBLA and the RTCs is the latter's supply of plasma to the former. We have already dealt with plasma supply in some detail (see paras 6.49 to 6.63). It must be emphasised again that BPL is entirely dependent upon RTCs for plasma for fractionation. In the light of this dependence of BPL on the RTCs we are suprised at the lack of formal management arrangements and links between the two.

10.7 As far as we can discover the director of BPL can only influence RTDs and RHAs in their planning to provide plasma via the indirect path of representation to the Department which then issues advice to the regions which may or may not be followed. The alternative is to attempt to persuade the directors meeting to some plan of action secure in the knowledge that even if the RTDs meeting agrees to a proposal, unless that agreement is unanimous, then some directors will not implement it anyway or RHAs may not provide the funds.

10.8 The relationship between CBLA and RTCs has yet to be tested at its most critical nexus. At present the fact that RTCs do not meet their plasma targets is not critical because BPL is not at full production. However, in the not too distant future BPL will reach full production and eliminate the plasma mountain presently in store. At this point any shortfall in plasma supplied by RTCs will directly affect BPLs productivity. It is not clear what BPL would do in this situation. The purchase of commercial plasma would presumably be barred by the Department since it undermines the concept of self-sufficiency and in any case would be considerably more expensive than RTC collected plasma (if the cost justifications for Elstree are correct).

10.9 Lest the account of the situation appear one-sided we would also point out that RTDs need to be able to influence CBLA planning. They need to be able to convince BPL of problems which the collection of plasma causes for them in the carrying out of their other (and to many of them their primary) function of supplying blood and products to hospitals.

10.10 The failure of co-ordination and communication between RTCs and the CBLA has unfortunately led to a certain amount of mutual suspicion and ill-will. We have found a number of examples of failures in communication or co-ordination:

10.10.1 it would appear that in the past BPL requested that RTCs attempts to process as much of their plasma as possible within 8 hours of collection to maximise the preservation of the Factor VIII content. This led some RTCs to lay on evening processing shifts. At the time of our visit to BPL we were given to understand that plasma is now processed in mixed RTC batches such that 8 hour plasma from one RTC may be mixed with 18 hour from another. This makes questionable the benefits of the 8 hour plasma. Since evening shifts cost RTCs more money, and notwithstanding that they may have been required to process platelets as well, it seems to us that RTCs should have been informed of the change of policy so they could take account of it in their production planning;

10.10.2 the attempt to co-ordinate arrangements to transport plasma to BPL has been described (see para 8.26-8.28). Despite the apparent agreement of RTDs to the plan to purchase freezer-trailers progress has been slow and at least one RTC has made alternative (and expensive) arrangements;

10.10.3 in the chapter on blood products we have indicated the lack of formal targets for the collection of specific plasma and this resulted recently in BPL having to purchase commercial Anti-D immunogloblin to make good a shortfall in their production. BPL blame this shortfall on RTCs failure to supply raw material; not all the RTCs agree and some blame BPL for the failure of one of their batches during processing;

10.10.4 that BPL policy may not always reflect the needs of RTCs is perhaps illustrated by the commissioning of the wedge pack (see para 5.92) for plasma fractionation. Apart from being designed to be mechanically opened at BPL it was also considered by BPL that it would secure more plasma for them in that blood bled into a pack with a wedge satellite cannot have it's plasma used for any purpose but fractionation. The effect has been the opposite of that intended. Because of the lack of flexibility of the wedge pack at least two RTCs will not use it all and others minimise the number of donations taken into wedge packs so as not to prejudice their production flexibility. BPL has therefore had to develop equipment which will enable a range of packs to be dealt with;

10.11 It is to be hoped that the above examples demonstrate the serious nature of the failure of communication between RTCs and CBLA and also something of the range of areas which are of mutual interest to the two organisations. In recognition of the interdependent nature of the relationship CBLA have sought to remedy problems by the appointment of a marketing director with responsibility for liaison with the BTS. Possibly the degree of co-ordination required is such that stronger organisational links are necessary.

Future role of CBLA

10.12 There has been much discussion between CBLA and the Department as to the precise nature of their role in the future. Whilst it is accepted that their primary role is to provide blood products for the NHS it is also proposed that BPL sell surplus products on the open market. This situation has arisen because, in achieving self-sufficiency in Factor VIII and Albumin, BPL will produce a surplus of other products and fractions. It is envisaged that the sale of these products would facilitate recovery of the capital cost of building the new fractionation plant. BPL will therefore to be competing with commercial pharmaceutical companies in the sale of it's products.

10.13 It might be thought that this area of CBLAs activity has little or no impact on RTCs. However BPL will presumably need product licences to sell it's products and to obtain these it's suppliers of raw materials, including RTCs, may have to conform to certain standards and practices. Consequently it could fall to RTCs to undertake additional testing etc. In addition it is

likely that RTCs and RHAs will be interested in the fate of any profit CBLA makes in view of the fact that they will have supplied the plasma. This is one of the factors which has given rise to the suggestions of cross-charging for plasma and blood products between RTCs and CBLA. This issue is discussed in appendix 1.

10.14 It is not within our remit to examine the future viability of BPL as a commercial enterprise. It is however relevant in so far as it may have implications for the relationship between CBLA and the BTS in organisational terms. The above examples illustrate that aspects of policy consideration about CBLA may appear remote from the BTS but often have a direct or indirect impact. It is also worth noting that sometime in the short to medium term (estimates vary from 2 to 10 years) genetically engineered Factor VIII will be available. This may remove the need to fractionate plasma to obtain it. Dependent upon whether artificial albumin and immunoglobulin are also available these developments may diminish, or eliminate, CBLA's role within the BTS. This fact needs to be recognised in developing any new organisation for the BTS. We discuss the possible options for the future place of CBLA within the BTS in Chapter 11.

11. THE FUTURE

11.1 The previous chapters of this report identify four underlying problems confronting the BTS, these are

11.1.1 the absence of reliable management information;

11.1.2 the inability of two London regions to meet the needs of their hospitals from within their existing collection programmes;

11.1.3 the absence of co-ordination between individual RTCs and also between the BTS (the collective RTCs) and CBLA.

11.1.4 arising from 11.1.1 and 11.1.3 apparent inefficiencies both within and between individual RTCs.

11.2 The data produced throughout the report on the individual aspects of the service illustrates the differences and variations which exist within the BTS on a range of fronts. Whilst the information serves to illustrate the underlying problems outlined in the preceeding paragraph it does not necessarily indicate the existence of problems in each individual aspect of the service. The major difficulty here is one of definition and perspective. For example the fact that one RTC is able to collect more donations with fewer staff than another RTC is a piece of information which should be, but is not, available throughout the BTS to enable management to effectively monitor individual performance. The absence of this sort of information is in our view a problem. Equally the operational situation that such information describes may suggest inefficiency if viewed either from the centre or within the context of regional independence and accountability. From either perspective management might expect for example the return on the resource devoted to the collection effort in each RTC to be capable of broad comparison.

11.3 In our view the problem facing the BTS are in essence structural and therefore lend themselves to organisational solutions. At Appendix 1 we also examine whether the existing method of financing the BTS could be changed on grounds of either efficiency or policy. We conclude that the financing arrangements do not of themselves create the problems which we have identified

within the BTS and changes to these arrangements would not of themselves resolve the problems. However we recognise that there may be policy aspects which make such a change worthy of consideration. In the succeeding paragraphs we therefore present three main organisational options plus two further options that are essentially composites of these. At Appendix 1 we suggest that if financial change is deemed necessary or desirable it can be introduced within any of the options. Each of the options has its advantages and disadvantages. In the discussion of each option we identify which of the problems detailed at paragraphs 11.1.1 to 11.1.4 would be likely to be resolved. It will become apparent that whilst each option is capable of resolving the problems the speed and likelihood of achieving that resolution differs. Each of the options assumes that the system of common management information detailed in Chapter 9 will be introduced to facilitate realistic planning and accountability.

OPTION 1 - The Minimum Change Option

11.4 This option suggests that some of the problems detailed at 11.1.1. to 11.1.4 can be resolved by a process of evolution without any change to the existing organisational structure except for the introduction of the uniform management information system. The option is based on the following premises:

11.4.1 RHAs are beginning to take more interest in their Transfusion Service. Several regions have undertaken management reviews in order to improve management structures and performance. It is likely that greater accountability will result and as the General Management concept settles into Regions this process will continue. In addition all regions are experiencing the effects of financial constraints. These factors have already led some regions (and will eventually lead all of them) to an objective examination of levels of funding and the cost/benefit relationship of resources invested in their transfusion service;

11.4.2 a prime function of the transfusion service is to provide blood and blood products to hospitals. It has for nearly forty years been a regionally based and administered service. The NHS is a regionally organised service and it makes sense to have a regional connection between an RTC and the hospitals that it serves. RHAs are the controlling management bodies for hospitals which are a crucial factor in the efficiency and cost effectiveness of the RTC. To retain the management and funding link between the RTC and hospitals provides a mechanism for consideration of the balance of issues in relation to both parties (although we have seen little evidence of such a process). It is, in the final analysis, for an RHA to determine what service it provides and to be held accountable for it;

11.4.3 there are undoubtedly varying levels of performance and efficiency in the BTS and individuals and hospitals in different regions receive a different serivce. Such problems are inherent in a regionally organised service, they are not peculiar to the BTS and apply equally to the NHS as a whole and are the price which is paid for the accepted system of organisation. As the NHS is a regionally organised service there is considerable logic in the argument for a regionally organised BTS;

11.4.4 it can be argued that RTD's have succeeded in collaboration and co-ordination on some fronts and are now more aware of the need for re-consideration of some current issues and for greater co-ordination. The call for this study is evidence of the need to address the way in which the service is organised. The study has brought a range of issues to the fore and the proposed management information system will highlight others. Therefore it is not unreasonable to suggest that some of the more desirable "changes" will evolve anyway without the need for organisational change. It would not be necessary to undergo organisational change in order to take advantage of some of the opportunities for savings eg the national purchase of blood packs;

11.4.5 the problem of supply and demand is not in essence intractable. Some 80% of the regions are self-sufficient or in surplus and there is no indication that this position will change in the foreseeable future. There is no inherent reason why each region cannot obtain enough blood to satisfy its own needs, it is purely a question

of being prepared to provide the funds to do so. If those regions which at present regularly subsidise those in deficit cease to do so then the regions in deficit will have to react to the situation or face the consequences. If some regions continue to have a surplus then they will decide what to do with the excess blood: either to continue to subsidise other regions deficits or alternatively demand an "economic" price. Several regions have indicated that they would be prepared to bleed "on contract" for other regions. It has been suggested that the AIDS situation is now causing clinicians to look more critically at their usage of blood. Clinical budgeting, which could include a charge for blood and blood products, may also have an impact on demand when it is eventually introduced;

11.4.6 the plasma target which is required for the effective functioning of BPL has not yet been reached. However despite many grumblings all regions have plans to meet their targets, albeit with timetables different to those originally envisaged. This is less of a problem given the delay in the new BPL plant coming into production. Some regions have threatened to "go commercial" on plasma fractionation if the delay, and thereby the increased costs they have to bear, continues. Even this, whilst understandable, is preventable either by statute or an injection of cash into regional budgets.

Disadvantages

11.5 This option suggests therefore that reform and improvement will evolve as a natural consequence of events which are taking place and that the only change necessary is the introduction of the Management Information System detailed at Chapter 9. There are in our view several drawbacks inherent in the option which must be recognised:

11.5.1 it does nothing to set on a clear organisational footing the relationship between the RTCs and BPL and will therefore not resolve the problem identified at paragraph 11.1.3. We are of the view that the two organisations are inextricably linked with decisions and actions in either place impacting on the other. BPL is the fractionation arm of the BTS; as such it is necessary to bring the parties together in some way to avoid the difficulties we have discussed in chapter 10. The

need of RTCs to have production flexibility to meet clinical demand for products, is as important as the need for BPL to receive guaranteed supplies of plasma, of adequate quality, to satisfy technical and legal production requirements. To strike such a balance requires acceptance by each party of the other's position and recognition that in particular areas one party has the expertise, and thus should have the final say, whereas in others both parties have valid operational views and compromise is required. It should theoretically be possible to achieve this without any major organisational change but the nature of the decisions that are required, and the likely funding implications suggest that to depend on this new relationship evolving "naturally" could be giving a hostage to fortune, particularly when the new BPL plant comes into full production;

11.5.2 the second major weakness in this option is the reliance on the ability and the will of both regions and RTD's to evolve uniform policies and procedures without an organisational impetus to stimulate the process. The track record of all parties to date does not inspire confidence despite a stated recognition, at least by RTDs, that such progress is desirable and necessary. Although the proposed management information system will encourage both outward comparison and inward examination it has to be recognised that the system, whilst comprehensive, could not be of a scale to encompass all the issues in question, particularly where there are no direct or apparent cost/performance implications. Even with a strong commitment from RTDs it has to be recognised that, with RHAs continuing to control financing, decisions agreed by RTDs (and BPL) could founder if RHAs refused to provide the necessary funds. It has to be recognised therefore that this option will require a significant departure from past form to enable the problems of co-ordination and inefficiency, (paras 11.1.3 and 11.1.4) to be effectively resolved even with the new management information system;

11.5.3 finally it is also necessary to recognise that the evolution of a regional solution to the supply and demand problem, whilst achievable, could be painful. It is unlikely that the gradual reduction in assistance to those regions which are in deficit would instantly provoke a corresponding investment of effort and money to

make good the shortfall. A more likely scenario would be the search for assistance becoming more desperate: haggling over prices and a lengthy examination of the relative costs of importing, self sufficiency and contract bleeding. In the interim the effect on hospitals and patients could mean the cancellation of operations and delay in the introduction of new specialties. There is also the likelihood of a degree of adverse (and to an extent unanswerable) public criticism before deficit regions would be forced to regularise their situation.

CONCLUSION

11.6 The existing organisation with the addition of a uniform management information system does provide a structure which would theoretically enable the resolution of all of the problem identified at paragraphs 11.1.1. to 11.1.4 with the exception of BTS/CBLA co-ordination. The primary question in consideration of this option is the speed and likelihood of solution.

OPTION 2 -The Intermediate Option

11.7 In our view it is not a realistic proposition to separate executive and financial accountability. It is not therefore, we suggest, feasible to seek to enhance the role of existing bodies within the BTS by giving them executive powers and yet to continue to provide the funds which govern the implementation of decisions and policies to the RHAs. Equally it is not feasible to fund RHAs to provide a service in which operational and policy decisions are made by bodies which are not accountable to them. We therefore present the intermediate option which envisages that executive and financial accountability remains with the RHAs but the advisory role of existing bodies be enhanced by redefinition of their remits. Additionally a new committee should be created to tackle the question of BTS/CBLA co-ordination. The decisions and recommendations of the enhanced advisory structure, detailed below, would need to be recognised as being of sufficient authority so that real account is taken of the merits and demerits of the situation before a veto is applied by an RHA. The constituent parts of the advisory structure would be as follows:

11.7.1 the RTDs committee could be given a specific remit to consider problems common to RTCs or of national significance and to issue policy and guidance on such matters. It would be expected that RTDs would

implement such policy and to facilitate monitoring of this copies of guidance issued should be provided to appropriate RHA and DHSS personnel. In particular the Committee would mandate it's representatives on the RTC-CBLA co-ordinating committee (para 11.7.2) and the Advisory Committee on the Blood Transfusion Service (ACBTS) (para 11.7.3). This RTDs committee should be seen as the representative body of RTCs. Where the RTDs committee felt any decision had implications for RHAs and/or the DHSS it would be referred to the ACBTS;

11.7.2 a new committee could be established with joint representation from RTDs and CBLA. The object of this committee would be to discuss and resolve issues affecting both RTCs and CBLA. The RTDs committee could send 3/4 representatives and CBLA a similar number. We would suggest the CBLA representatives should include the Chief Executive and the Directors of BPL and BGRL. As with the RTDs committee it would be expected that decisions of this joint RTC - CBLA committee would be implemented by all RTCs and CBLA. The joint RTC - CBLA Committee would refer matters to the ACBTS in the same way and for the same reasons as the RTDs committee. Its decisions would also be notified to RHAs and DHSS;

11.7.3 the ACBTS should also have it's remit redefined and would need a higher profile that at present. It would have a multi disciplinary membership, as now, to ensure that all views, particularly those of regional management are represented. Its role would be to consider references from both the RTDs committee and the joint RTC/CBLA co-ordinating committee and to decide thereon. On issues of particular importance it would refer its decisions to the Department and the latter could well decide to issue these as advice to RHAs/SHAs and to follow them up in the accountability review process; in other cases it's decision would be final. Additionally the ACBTS would continue to act in its' present capacity as a sounding board for initiatives and policy considerations from the Department.

In the last resort however it must be recognised that individual RHAs and SHAs would still be able to veto the implementation of the proposals of any of the committees thus preserving their statutory autonomy. It would be hoped however, that if the committees can gain recognition, then RHAs/SHAs would consider the issues very carefully before deciding to ignore their advice.

Disadvantages

11.8 We recognise that these proposals could be argued to be a cumbersome structural sledgehammer to crack what is in NHS and overall financial terms a small nut. We also accept that the situation as described in the BTS could apply equally well to other areas of the NHS. However the proposals, which are not organisational changes per se but rather attempts to improve communication and liaison, could perhaps provide a little more momentum and impetus than the minimum change option. The proposed structure would provide a hierarchy of committees via which all interested parties could express their views but which at the same time would have as their objective the application of more uniform solutions to problems than has been possible in the past.

11.9 The difficulty of this whole approach is that history is very much against it. Committees with similar aims have been formed in the past. They have had little success in getting their decisions implemented. There has always been a reluctance on the part of the Department to do more than "strongly commend" certain policies to RHAs. In the final analysis if funding is continued via RHAs then they must have the right to disburse their resources in the light of their priorities and justify their judgement and performance through the normal accountability process.

CONCLUSION

11.10 This option tackles the problems left untouched by option 1 namely that of co-ordination between the BTS and CBLA. It can therefore be said to offer a solution to all of the problems identified at paragraphs 11.1.1 to 11.1.4 but is subject to the same considerations over speed and likelihood of solution.

Other Considerations

11.11 We have also considered other intermediate options: the possibility of separating functions of the BTS to provide dual lines of funding and accountability; or discrete areas of funding for specified purposes. This could involve, for example, ring-fencing that proportion of the budget related to plasma production.

The major purpose behind such considerations is to seek to find a method of ensuring that sufficient plasma of the required quality is available to CBLA to enable manufacture of products for self sufficiency. In essence this means that CBLA would need to be able to impose conditions on the quantity and quality of plasma and to achieve this would mean that the harvesting of plasma would need to be funded either centrally or by CBLA.

11.12 Blood is, in BTS terms, a multi-purpose product. Although the vast majority of donations are processed, plasma is only harvested from about 50% of all donations. Not all plasma is destined for processing at CBLA - about 10% of all plasma is issued to hospitals as clinical FFP. The vast majority of blood donations are used by RTCs either as whole blood or RTC made products. Consequently it must be recognised that the collection effort is not plasma driven. Whilst in terms of CBLA plasma is the primary product, in RTC terms it is but one of many. This being the case it could be argued that RTCs collection and processing efforts would not be much influenced by funding from an outside source eg either DHSS or CBLA which only covered the cost of harvesting of plasma.

11.13 It is likely therefore that to achieve any meaningful influence or effort it would be necessary to fund the entire collection and processing cost. This has superficial attractions but on examination raises several problems. RHAs would still presumably be responsible for the provision of supplies of blood to hospitals but would be deprived of financial control which would place them in an impossible position and would also prevent the funding authority from achieving the most effective collection effort by seeking to exploit cheapest areas. In terms of economies of scale as RTCs would continue to be independent it would not offer much and indeed would probably result in increased administrative cost at the funding source. We conclude therefore that it would be better to go the whole way to a national organisation for the BTS rather than pursue this tangent and this option is detailed in the succeeding paragraphs.

OPTION 3 -The National Option

11.14 This proposal envisages the creation of a National Blood Transfusion Service organised, managed and funded centrally. The most appropriate vehicle for this service would be a Special Health Authority.

11.15 The Authority would be responsible for the collection, testing and processing of blood, the distribution of blood and products to hospitals and advice on their use; the provision of a blood group reference service; and the provision of plasma to CBLA, under powers delegated by the Department. These would be the core functions of the NBTS and its initial remit would be limited to these functions. The Authority would be responsible to the Secretary of State for the provision of the service within broad departmental policy guidelines. The Authority would delegate operational policy and strategic matters to a National Director/General Manager whose prime function would be to manage the organisation. The directors of the existing centres would be in a line management relationship to the National Director/General Manager: responsible and accountable to him/her.

11.16 Also in a line management relationship to the National Director but not to the RTDs would be a series of operational policy heads namely:

Head of Medical Operations
Head of Scientific and Technical Operations
Head of Collection and Distribution Operations
Head of Finance and Personnel (also responsible for the Management Information system)

These individuals would be responsible for the operational policy, planning and provision of advice to the National Director in relation to their particular disciplines. The National Director would be the final arbiter of all decisions and the individual who would be accountable to the Authority. The operational policy heads would not be career progression posts but individual appointments at a particular salary eg we would not envisage the Head of Scientific and Technical Operations as being a particular PTA or PTB grade. We see the role of the policy heads as crucial to the success of the structure. Their existence is necessary to make the role of the national director viable.

11.17 The policy heads would require a series of links both formal and informal with their specialties in the transfusion centres: eg they would be members of (perhaps chair) the various professional committees. They would be responsible for the formulation of policies in conjunction with these committees to tackle the range of issues confronting their disciplines and the inter relationship with the other disciplines within the advantages offered by

a national framework. The range of issues which, in our view will need to be addressed by the new authority is considerable and has been detailed throughout the report. On the following page we produce a possible organisation chart and identify some of the major issues which each policy head will have to tackle. In the initial stages we assume that, particularly on the non medical side, each "issue" will require at least one individual to deal with it. It could be that this is an over-estimate however we do not wish to understate the extent of the task. In the longer term the size of the central resource could reduce. Initially however we estimate that the resource requirement will be of the order of 40/50 posts. The organisation chart identifies 44 posts, ranging from secretarial/typing through to senior administrative and consultant levels. Additionally some management services expertise would be of advantage, at least initially.

11.18 The levels of salary etc will have to be decided. For the purpose of costing we have assumed that the salaries will have to be sufficiently high to attract individuals of an appropriate calibre and have therefore allowed £45,000 for the National Director, £35,000 for the policy heads, £15,000 for the support staff to the policy heads (except for the Associate Specialist post) and £8,000 for the General Office/Admin section. The staff cost of the HQ organisation could be of the order of £750,000 per year. Premises will have to be provided and whilst this cost will depend on location, size, whether bought or rented etc, it is reasonable to assume an accommodation cost of about 25% of staff costs per year ie of the order of £190,000 per year. Allowing for common services such as telephones etc the running costs of the HQ organisation would be in excess of £1 million per year.

NATIONAL DIRECTOR

Head of Medical operations (Consultant Grade)	Head of S&T operations	Head of Collection and Distribution	Head of finance and personnel	General office/ admin section
(1) Assoc Specialist (2) Non Medical Support Staff	(8) Scientific and technical Support Staff	(6) Support Staff	(14) Support Staff inc (2) Cost accountants.	8 staff typing, telephones, correspondence, reception, messengers etc.

TASKS	TASKS	TASKS	TASKS
(a) Bleeding Policy	(a) Staffing Structure	(a) Collection methods, locations, performance and policy	(a) Financial Planning (2)
(b) Medical Training	(b) Range of Serological and Microbiological testing	(b) Plasma procurement	(b) Central purchasing/ supplies (1)
(c) Medical Donor problems	(c) Production performance	(c) Distribution arrangements	(c) Personnel (3)
(d) Medical Recruitment	(d) Standard operating procedures	(d) Publicity and market research	(d) Management Information System (4)
(e) Research	(e) Reagent production	(e) Donor records.	(e) Payroll (4).
(f) Liaison with hospitals.	(f) Research		
	(g) QA/QC		
	(h) Liaison with hospitals.		

11.19 The policy heads, the National Director and the Chairman of the RTD's committee would form the "management board" of the NBTS. The transfusion directors, as managers of the operational arms of the service, would be responsible for the implementation of the decisions of the Management Board and accountable to the National Director. The Transfusion Directors committee would continue as a forum for them to meet and discuss problems etc and make submissions to the management board. Their line of communication would be to the National Director who would also sit on the directors committee.

11.20 We recognise that the span of control of the National Director will be, in line management terms, wide. His/Her role however will be to hold RTDs accountable for their performance in the implementation of policy. The policy heads will be responsible for the monitoring and evaluation of performance within their disciplines and for the provision of assessment and briefing advice to the Director. We suggest therefore that his/her task is containable.

11.21 The option provides the opportunity to either include or exclude CBLA. In our view the structure suggested is valid in either eventuality. The option is discussed further below. However if CBLA is to be included then it is envisaged that an additional operational head would be included on the management committee ie the Head of Manufacturing operations.

Location of the proposed SHA

11.22 We have not identified an existing location within the BTS which could readily accommodate the new SHA headquarters proposed. A cost will therefore be incurred in housing the organisation. A London location would provide ready access to officials and Ministers but this would entail a far greater cost than a provincial location. Given the nature and identity of the new organisation it is possible that there could be considerable "morale" as well as cost advantages in a provincial location and these might well outweigh any perceived advantage arising from a London location.

Funding

11.23 We assume that initially at least the new SHA would be centrally funded by DHSS on the same basis as all other health auhorities. We discuss in Appendix 1 the question of cross charging and "stand alone" financing. The complexities of the existing functions and funding arrangements of the BTS

mean that it is not feasible to establish the new organisation overnight. Some RTCs undertake functions which others do not eg ante natal testing and tissue typing. The remit of the new SHA would have to identify the authority's functions and it would not be feasible to set the parameters of that remit to encompass all functions undertaken by every RTC - it would have to be set at the minimum core functions. Consequently central funding would only be provided for these core functions.

11.24 It will be necessary to establish what proportion of RTC funding is provided for core functions - the difficulties encountered with the existing costing information indicate that this is likely to be a fraught and tortuous process but eventually RHA budgets will be reduced and the SHA budget established. The new organisation will have to decide whether RTCs are to continue to provide the peripheral functions and how they will be funded. It is quite feasible that grants or contract arrangements could be established between individual RHAs and RTCs or the SHA. It will also be necessary to consider the position of the existing Consultant Medical staff who are under contract to RHAs at present.

The Role of CBLA in the proposed organisation

11.25 We conclude at paragraph 11.21 that the proposed structure is in our view valid whether or not CBLA is included. It is possible to envisage a situation where CBLA continues to operate outside the proposed SHA for the BTS. We have discussed in earlier chapters of this report the role of CBLA in relation to the BTS and conclude that operationally and organisationally it makes sense for CBLA to be part of the mainstream NBTS structure although we recognise that there could be longer term "strategic" considerations which could outweigh this view.

11.26 If CBLA forms part of the NBTS we suggest that the existing Chief Executive post at CBLA becomes head of manufacturing operations accountable to the National Director. The identity of CBLA would be subsumed within that of the new NBTS SHA and the existing SHA could be abolished.

Disadvantages

11.27 It must be said however that the national option is not without disadvantages. It will entail investment in the initial stages without any major compensating savings in the short term. It could be argued that the eventual scale of saving achievable through the national option does not justify the investment required or the upheaval that it would cause.

11.28 The separation of management and funding of the consumer (ie hospitals) from that of the supplier (ie RTCs) could remove the impetus and opportunity provided by the introduction of the MIS under continued regional management to tackle those elements of inefficiency which are the responsibility of hospitals. Although it is, in our view, vital that the RTCs under the new organisation continue to foster good relations and communication with their customer hospitals, the creation of a separate BTS could remove any regional interest in encouraging hospital efficiency. The new SHA could thus become an increasing drain on resources as it would be seeking to meet demand (as now) but have a greater capacity to do so than now. The only control would be the cash limit imposed by DHSS which could be challenged by the SHA on the basis of increasing demand.

11.29 We have been disturbed by the general lack of formal mechanisms in planning processes to ensure that the effect of developments in hospitals are notified to RTCs so that they can take them into account in their own planning. The separation of the RTC and RHA may exacerbate this situation.

11.30 The underlying motivation of blood donation is that of the "gift relationship" it is socially desirable and should be encouraged. Consideration of the national blood collection programme on a cost effective basis could lead to areas of the country being deprived of the right to donate and thus undermine the ethos of the BTS.

11.31 Finally the NHS is a regional service operating within broad national policy guidelines. It recognises regional differences and requires RHAs to provide the health service to its region. A nationally organised BTS is counter to this philosphy.

CONCLUSION

11.32 The chief advantage of a centrally funded and managed BTS is, as noted earlier, that it provides the most certain method by which organisational change, and hence cost savings, can be achieved. It alone provides the potential to completely and effectively rationalise the blood collection and processing functions; the location of centres in which these tasks are undertaken; and to ensure that supply and demand can be balanced and the requirement for plasma achieved. Furthermore it offers the best prospect of achieving uniformity, where this is desirable, and co-ordination throughout the BTS.

11.33 The national option has these advantages because the tasks detailed above will be carried out by one organisation, setting its own priorities and undistracted by the administration of other health service functions. In addition this option provides a corporate identity for a service which undoubtedly has aspects which transcend regional boundaries. Finally, amongst those staff in the BTS who see the need for organisational changes - and we would say from our discussions that they were in the majority - the setting up of a truly national blood transfusion service has considerable support.

Variations on the National Options

11.34 We briefly outline here some of the other possible central organisations which we have considered but decided not to pursue and explain the reasons for the rejection.

11.34.1 we first considered whether the arrangements that exist in Scotland would be workable in E & W. There is a National Director of the SNBTS who chairs a committee composed of the directors of the five Scottish RTCs and the director of the fractionation centre. The National Director has no executive power over the other directors, he is a consultant as are the RTC directors and there is no line management accountability between him and the other directors. Leaving aside the involvement of the Scottish Office and Common Services Agency the directors essentially provide a committee which runs the SNBTS on a consensus basis. The National Director is not the manager of the SNBTS and the individual directors are all autonomous managers. Although there is a degree of co-ordination in the SNBTS which does not exist in

E & W it would be wrong to think that it is a fully co-ordinated service. The National Director expressed the view to us that much greater co-ordination is both desirable and necessary in Scotland and that could only be achieved by investing some executive power in the post of National Director. In our view the Scottish Model would not readily translate to E & W for two main reasons. Firstly there are 14 RTCs and a fractionation centre which would be form too unwieldy a body for consensus; secondly and more importantly, we have identified throughout this report and throughout the organisational options the need for the BTS to be managed. This being the case we feel that a structure is required which provides clear lines of executive authority, accountability and responsibility throughout the system;

11.34.2 we considered a variation of the Scottish system which would provide an organisation that reduced the number of individuals involved. It could be argued that representatives of the RTDs could form a committee under the chairmanship of a National Director. The committee could, for example, consist of one director from each of the three existing divisions into which the BTS informally organises itself. The representatives could be elected or appointed on a rotation basis. We feel however that such an organisation has the same fundamental weaknesses as those identified in para 11.34.1 in addition to adding to the likelihood of failing to achieve consensus;

11.34.3 having concluded that a National Director/Manager with executive authority is an essential part of any central organisation we considered whether one individual could be appointed to whom all of the RTDs would be accountable. We are of the opinion that the issues identified in the report which a central organisation and National Director would be required to address are so wide in scale and scope as to render the task virtually impossible with such a simple structure. In addition, the span of control of the National Director, ie line manager of 14 RTDs, would be too wide for operational efficiency without the backup of a fairly extensive support staff. Finally he would be subject to a wide range of often conflicting advice which could be a barrier to effective decision making;

11.34.4 we finally considered whether it would be feasible to provide an appointed National Director/Manager with the organisation broken down into a series of groups, again perhaps based on the existing BTS divisions. Each of these groups could have an appointed group manager to whom the RTDs would be accountable and who would in turn be accountable to the National Director. Each of the Group Managers would require support staff of a similar nature to those identified in our proposed option as would the National Director (although his/her needs would probably be of a lesser scale) thus it is likely that the resource demand of this structure would be greater than that required in our proposal. Accountability to a Group Manager would remove the line accountability and advice input of the RTDs a stage further from the National Director and it is questionable whether this is either necessary or desirable. In addition the size of the structure (ie 14 RTCs) does not warrant so many tiers of management which could both dilute and replicate the decision making process.

11.35 We conclude therefore that a structure along the lines proposed in paras 11.14 to 11.24 is the most efficient and cost effective option for a national organisation to resolve the problems detailed at paragraphs 11.1.1 to 11.1.4.

The Composite Approach

11.36 In concluding this discussion of options we suggest there are an additional two options which can be derived from the package. Firstly it is possible to composite aspects of some of the options eg to adopt the minimum change option but also to establish the RTC/CBLA co-ordinating committee which is put forward in the intermediate option. Secondly progress can be phased so that the minimum change approach and the RTC/CBLA co-ordinating committee be adopted in the short term to enable the MIS system to be established and operated and to review the situation at a later date to see whether the MIS has encouraged the evolution of reform and it not to then move to a national organisation.

12. COST IMPLICATIONS OF THE OPTIONS

Information System

12.1 We recommend at paragraph 9.20 that a uniform management information system be established within the BTS. In order to avoid understating the set up cost we have assumed that it will be necessary to buy in expertise to assist in this process. The cost of such expertise, if it proves necessary at all, will obviously depend on whether it is sought from RHA, DHSS or private consultants and the length of time for which it is required. To put a figure to the cost we have calculated on the basis of what NHS MCS costs would be to to do the work. Over a year two consultants would cost of the order of £100,000 including expenses. In the light of the systems expertise within the BTS it is unlikely that an investment of this scale would be necessary.

12.2 In addition to the development cost it may be necessary to provide a staff resource to monitor the introduction of the MIS and deal with any problems arising from it. We estimate that such a resource would need to be available for about six months and would cost at most £50,000. If the national organisation option is implemented this cost would be subsumed within that structure and thus would not require additional resources over and above that required for the national organisation as a whole.

12.3 The information collected would need to be collated and scrutinised centrally at the DHSS and this would place an additional burden on HSI. This branch would require an additional manpower resource which we estimate to be about half an HEO post (approximately £13,000 pa). The introduction and assessment of a short term crude information system would also need to be overseen by HSI and it is likely therefore that the total additional manpower resource required in HSI would be 1 HEO post (- about £25,000). We have not attempted to assess the present staff loadings within HSI and have assumed therefore that the additional tasks will require additional resources.

12.4 We estimate therefore that the total once and for all cost of the development and introduction of the information system will be about £150,000 with a continuing cost of about £25,000 (based on 86/87 costings).

Organisational Options

12.5 Broadly the minimum change and intermediate option would be at nil cost above that required for the MIS outlined above. The changes envisaged with the intermediate option would demand a slightly higher DHSS involvement. In real terms this is likely to mean a committment to more meetings at Principal, Assistant Secretary and Principal Medical Officer level. As such it is difficult to assess in cost terms however and the overall situation in HSI would need to be monitored initially to assess the increased demands on the branch.

12.6 The national option would impose a running cost of about £1 million per year (staff and on-costs) above the existing cost of the BTS. Obviously the cost would be determined by actual salaries paid and in our estimate of this we have attempted to err on the side of caution but at the same time not under-value the posts. Details of the structure and our estimate of the salary level are contained at paragraph 11.14 et seq which explains the option.

12.7 The establishment of the national organisation would also have a one off cost to recruit staff, obtain premises etc. We are unable to put a figure on this as it will depend on a wide range of variables. It is unlikely to exceed £150-200,000.

Savings

12.8 Any discussion of savings must be edged round with caution. The absence of a system which relates staffing to workload and the range of variety in operational practises and performance makes discussion in terms of staff numbers a sterile exercise. We have to resort therefore to attempting to assess the potential from the only available costing information - the Cost Form 60, which, as we have indicated throughout the report contains known distortions.

12.9 The information contained within the Cost Form 60 enables the calculation of a cost per donation. The number of donations is one of the few constants in information terms among a sea of variables. The cost per donation will be distorted by the range of service provided, or functions

carried out, by the RTC. Interestingly the cheapest RTC in cost per donation terms provides a full routine ante natal service. However if all centres were able to achieve the cost per donation of the cheapest then a saving of at least £6 million per year may be possible.

12.10 In an attempt to offset the functional differences between centres it is possible to exclude from consideration that part of the budget which is allocated to "technical services" It is necessary to restate the need for caution here because as we indicate earlier in the report it is apparent that regions allocate their technical service costs in different ways. Having stated this caveat we can then examine the costs which are stated for collection, grouping, processing and distribution and express these as a cost per donation. The total cost of these activities is slightly less than £45 million per year. If every centre were able to achieve the cost of the cheapest in each category this would produce a total cost of about £29 million and therefore a suggest potential for savings of up to £16 million per year.

12.11 The operational variety which we have discovered in our view indicates that savings (possibly considerable) are available. The only available information suggests that the potential for savings from the rationalisation of organisation and operations ranges from £6 - £16 million per year. In our view these figures must be treated as suggesting broad orders of magnitude rather than targets for savings. A more realistic assessment can only be made when the management information system is functioning.

12.12 We suggest at paragraph 5.116 that there is potential for additional cost arising from the rationalisation of QA/QC practices and this could require up to an additional 50 posts. Depending on grade we estimate that this would cost about £500,000 per year and should be offset against the savings figures discussed above.

12.13 It will be seen from the foregoing that there is potential for savings and the indications are that they would be of sufficient magnitude to make the consideration of organisational change worthwhile. We must point out however that such savings as exist within the BTS are, in our opinion, available (at least in theory) under any of the organisational options we present. This is subject to the provision that the management information system is implemented uniformly and the information it generates taken account of. Thus the required rate of achievement of the savings becomes a significant factor in deciding what organisation to opt for.

12.14 The minimum change option suggests essentially an evolutionary approach to change. It is reasonable to suppose that without an organisational dynamic the rate of change under this option will be slowest and therefore the achievement of savings may be delayed.

12.15 The intermediate option may inject some urgency into the pace of change but the fact that finance would still be in the control of, and therefore subject to other competing priorities within, the RHA would suggest that the achievement of savings could be uneven throughout the NHS.

12.16 The creation of a national organisation would mean that the central body could set as a priority the achievement of change and hence savings. With no competing claims to distract it is reasonable to suggest that savings might most rapidly be achieved by a centrally organised BTS.

12.17 Apart from the rate at which the proposed organisations can achieve the potential savings we must also consider their ability to do so. Whilst it is clear that there are no organisational barriers to prevent a centrally managed BTS from doing so this is not so certain if management were left with the Regions. It is not realistic to expect each RHA to attach the same degree of priority to reviewing the operation of it's RTC. The savings, whilst significant when viewed globally, are in reality a fairly small proportion of an RHAs budget so that their achievement may have less urgency for the RHA than other areas. We have to conclude that there must be considerably less certainty of attaining the full potential savings within the BTS if it continues to be regionally managed.

APPENDIX 1

FINANCING THE BTS

Introduction

1. As required by the terms of reference we have examined the financing arrangements of the BTS in order to ascertain whether revision of those arrangements, particularly the introduction of charging systems, would either resolve any of the problems currently facing the BTS or generally place the BTS on a more effective and efficient financial base.

2. The existing arrangements for funding the BTS are detailed at paragraph 2.10 et seq. It is suggested that these arrangements give to the following problems:

2.1 the channelling of finance through RHAs means that central BTS initiatives which require substantial additional resources can be put in jeopardy. This is because the BTS is but one of a number of competing priorities within each RHA and because its funding is not "ring fenced" there is no certainty that each RHA will regard a particular development as being of equal priority eg the plasma procurement programme;

2.2 there is little or no awareness amongst either producers or users of blood products and services of their cost. It has been suggested that this can encourage profligate or inappropriate use;

2.3 the increased emphasis on containing costs is proving a disincentive to regions with surplus blood collection capacity assisting those which are short of blood;

2.4 the different accounting systems used by RTCs mean that no common costing information is available. This impairs the ability of management to assess the cost effectiveness and efficiency of RTC operations;

3. In addition it is suggested that the central funding of the CBLA produces particular problems for that organisation in that:

3.1 the method of funding does not allow CBLA to have any impact on RTCs ability or willingness to collect plasma by way of financial incentives;

3.2 its financing on an annual grant basis is a cumbersome proces for an organisation which needs financial flexiblity, especially the ability to make financial decisions quickly.

4. It is also relevant to consider developments in the context of the wider NHS where there is a general move towards financing the consumers of services to enable them to purchase those services they require, thus moving away from the concept of "top slicing" and in the process producing self financing and accountable units. The method of implementing this change in the BTS would be the introduction of charging systems for products and/or services. RTCs could charge hospitals for products and services supplied and could additionally charge CBLA for plasma supplied. Equally CBLA could charge for the products it manufactures. One particular system suggested is that of "cross-charging' between CBLA and RTCs - RTCs would receive a credit for plasma supplied to CBLA against the cost of products received from it.

Discussion of Charging Systems

5. It should be noted that charging systems can be implemented separately. RTCs could charge for their services and products without CBLA doing likewise and vice versa. Cross-charging between CBLA and RTCs could be introduced without extending the charging to hospitals.

6. There are as we indicate in paragraphs 2-4 of this appendix two clear considerations in the evaluation of these systems. The first is whether they would lead to greater efficiency in the production and usage of blood and blood products and resolve the problems facing the BTS which we identify in Chapter 11 of the report. Second is the policy consideration indicated in paragraph 4. Consideration of this latter issue is beyond our remit and we confine ourselves to commenting on the feasibility of the charging systems in this regard.

Price

7. Crucial to the discussion is the question of pricing. We assume that the aim of a pricing structure would be in broad terms to redistribute the money

currently spent through central funding of RTCs and CBLA rather that making either show a profit. Consequently the pricing policy would be to set a charge that recovered the cost of producing a given product.

8. At this point the first problem is encountered. The costing information currently available to RTCs for setting prices is that generated by the cost form 60 returns (see Chap. 9). We have already noted that these are a) inaccurate and (b) vary widely between RTCs. Assuming the problem of exact costing information could be overcome by introducing the MIS package suggested in Chapter 9 this would still leave the problem of different RTCs producing their products at varying costs.

9. In terms of an RTC charging its hospitals for blood etc the fact that in different regions hospitals would be paying different prices should not matter greatly. No doubt there would be grumbling from hospitals whose RTC was "expensive" compared to others but in fact setting a price would only make obvious what has been the case for years - some RTCs <u>are</u> more expensive than others. There may also be "border" problems where hospitals traiditionally supplied by an RTC outside their region find that their parent region's RTC is cheaper. We do not consider these problems sufficiently intractable to undermine the feasibility of intra-Regional charging should it be considered desirable on policy grounds.

10. The setting of a price for CBLA's products is also not unduly problematical. The the primary consideration is CBLAs prices in relation to that of commercial pharmaceutical firms. No doubt RHAs will be strongly encouraged to obtain Factor VIII etc from CBLA but we assume that it is unlikely to be given a statutory monopoly. CBLA's price will therefore need to be competitive and it could be undercut by a competitor selling Factor VIII or other blood derived products as "loss-leaders".

11. The chief pricing problem will be that of determining what the price of plasma should be. We have seen that the present costings, inexact as they may be, give a range of regional costs for plasma of £37.50 to £64.22 per litre for ordinary FFP and £23.93 to £42.81 for SAG(M) FFP. This means the "bill" for CBLA's 450,000 litres of plasma could range from £12-£29M per annum depending on what decision is made as to price.

12. The options are to set individual prices for each region, related to RTC production costs, or to set a national price. Individual prices could create an element of competition between RTCs if CBLA sought to maximise it's purchases from the cheapest regions. However the collection and processing of plasma is relatively inflexible ie RTCs cannot quickly scale up or down the process. It is therefore likely that some plasma target setting would still be required. It is unlikely in our view that any region would be allowed to cease plasma collection entirely simply because they decided the process was not cost effective.

13. A national price would create regional "winners and losers". The winners ie those for whom the price paid by CBLA exceeds the production cost would no doubt be happy with the situation although there would be no guarantee that "profits" would be invested in further plasma collection, or any RTC activity. The losers, ie those whose production costs exceed the price would of course labour under a substantial disincentive to continue plasma collection.

14. We conclude therefore that the problems associated with the setting of a price suggest that charging between CBLA and RTC is not the simple policy option that it may first appear to be.

Charging Systems and Efficiency

15. It has been argued that the introduction of charging would stimulate greater efficiency throughout the service and also, within hospitals, more careful usage of BTS products. We do not think the arguments for this are convincing. As regards clinical use of products we have discussed both wastage and inappropriate use in Chapter 6. If we accept the premise that both exist it is open to question whether charging will be effective in controlling either. It is true that a number of clinicians we spoke to agreed that charging for blood and blood products would cause them to think more carefully about usage. These were however in the minority and some qualified their response to the effect that it would only be effective as part of a general clinical budgeting initiative. Clinical budgeting is as yet in its infancy and it will be some time before it is universally established throughout the NHS. It should also be remembered that one of the products most often cited as either being wasted or inappropriately used is Albumin. Some 30-35% of this has to be bought commercially throughout England and Wales. Cost does not on the face of it appear to be a regulator of use in this case.

16. Turning to production efficiency it seems to us that charging for RTC products will not operate as a regulator of the RTCs efficiency so long as the product is supplied free to the recipient and there is no alternative source of blood and products with which the RTC has to compete for business. In this sort of set up the price itself becomes quite artificial and no true measure of demand for the product, nor even a very close reflection of the cost of production.

17. Given the pricing problems discussed above it is also questionable whether CBLA buying plasma would engender more efficient plasma collection. As we have seen the competition that can be created between RTCs is limited. Those regions that have some spare capacity are not necessarily the cheapest. Additionally reducing, but not eliminating the amount collected from an "inefficient" (ie expensive) region renders the plasma that region still supplies yet more expensive since overheads are not reduced proportionately with reduced collection/production.

18. In terms of CBLAs production efficiency it is hard to see how this could be improved by charging. Even if they produced a carefully costed charge for their products that was cheaper than their commercial counterparts this would not necessarily mean they were efficient as the profit element of the commercial's price cannot easily be determined. Realistically, the level of investment made in CBLA, and the sensitivity of the self-sufficiency issue, presumably mean that BPL could not be allowed to go the wall if it failed to corner the market because of the prices it charged. Efficiency could be equally well ensured through firm management control as through charging.

Charging systems and central initiatives

19. To what extent would charging systems assist CBLA and RTCs in implementing central BTS initiatives? Clearly the idea here is that charging would lead to RTCs and CBLA being financial independent and therefore able to dispose of their funds as they wish. The ability of either to be entirely self-financing is discussed further below. Assuming that both became largely self-financing units would this enable central planning and financing of central initiatives such as plasma procurement? Under this scenario RHAs are removed from the policy making process in so far as they could no longer directly refuse to finance, or under finance, an intiative. However there would still need to be a forum via which RTDs and the director of BPL could agree common

initiatives. Such a forum exists now at the RTD's meetings and it is clear that financing difficulties are only one (and possibly not the major) of the problems that prevent co-ordinated initiatives getting off the ground.

20. Even if RTCs achieved financial independence through introducing charging they would still have to meet hospital needs for blood etc. Unless they were taken formally out of RHA control (ie put onto a national organisation) they would still be the responsibility of the RHA and to that extent the latter would still wish to have a planning input. In our view therefore charging systems, without organisational change, will not solve the problem of financing central initiatives.

Charging and Management Information

21. The lack of management information and particularily costing information would certainly be diminished by the introduction of charging system provided the basis of the pricing policy was to establish the actual production costs. However, we see the need for a common MIS package so that comparison of performance from RTC to RTC can be made. RTCs should not therefore in our view be left to introduce their own charging systems in isolation. We would also question whether the MIS package should be led by the need for costings rather than being designed to cater for the information needs of all RTC managers.

22. We have shown that price determination would be critical in any charging system. It follows therefore that much of the work on costing would need to be done prior to implementing charging thus negating the argument that to charge will furnish the BTS with management information.

Charging systems and blood shortages

23. Could charging for blood between regions be a method of encouraging RTCs with the potential to collect blood in excess of their own needs to do so? This excess blood would then be available for purchase by regions that suffer a shortage. Four points need to be made here. Firstly, in the climate of financial stringency that curently exists no RTC is likely to supply blood or products for less than they cost to produce therefore different regions would charge different prices.

24. Secondly, simply to recover costs may not be sufficient incentive for RTCs with a potential surplus to exploit it. RTCs are subject to manpower as well as financial constraints and these could make difficulties for an RTC that required extra staff to realise it's surplus.

25. Thirdly, it is necessary to recognise the nature of the shortages that occur. All regions have opportunistic shortages from time to time and most have opportunstic surpluses. These latter surpluses arise because blood which an RTC planned to collect for its own use is not in fact required. RTCs are willing to give these surpluses away because otherwise they would remain unused. Whether they can be used by another region depends on whether anyone is in deficit at the same time. The introduction of charging into this opportunistic market will do nothing to increase the amount of blood available.

26. So to the fourth point: one or two regions have a consistant shortage that cannot be satisfied by opportunistic surpluses. They need to plan to satisfy this shortage ie they need a long term contract with a surplus region to make up their own collection deficit. This is the only way to ensure that blood shortage is kept to a minimum under the existing organisational arrangement. Such an arrangement does not require the introduction of charging by all regions, merely the netogiation of a contract between the interested parties. It is safe to assume that no RTC would embark on the speculative production of a surplus in the hope of finding a market. We therefore conclude that charging will not ease the problems of those regions that suffer a regular blood shortage.

Charging systems and cost awareness

27. Undoubtedly it would be advantageous for the cost of blood etc to be publicised amongst its users. This can be done without actually introducing charging. It is arguable that without clinical budgeting merely publicising the cost will have the same effect as actually charging. As we have noted earlier it is by no means clear that knowledge of the cost of a product affects clinicians usage.

28. It may be the case that once production managers in RTCs know their production costs they will seek to control them if they are high in relation to other RTCs. The important element throughout is knowledge ie information:

implementation of charging is not central to this. It must also be emphasized that the cheapest RTC in production terms will not necessarily be the most efficient (it may be cheap because of some extraneous factor outside management control) and a range of performance indicators are required to ensure a process is efficient.

Financing CBLA

29. CBLA's funding problems basically revolve around its standing financial instructions which are drawn up in line with Departmental and Treasury guidelines. Once again the suggestion appears to be that if through charging CBLA could become largely or wholly financially self-supporting than it would be freed from the restraints the standing instructions impose. We would suggest this view is naive. Unless CBLA is removed entirely from direct central government control then the Treasury will take an interest in its financial procedures, even if the Treasury supplies none of the money. If CBLA need more flexible financing arrangements then negotiations with the Department/Treasury would seem more profitable than reliance on charging systems.

30. The fact that CBLA does not pay for the plasma it gets from RTCs means that it cannot encourage RTCs that provide cheap or good quality plasma to produce more. Neither can it penalise RTCs whose plasma is expensive or of poor quality. Charging, it is suggested, would also allow CBLA some influence over the raw material it receives. However CBLA has only one supplier of plasma - the RTCs. It cannot threaten to stop taking plasma from one RTC unless it has already negotiated with another one of make up the defecit. Realistically CBLA needs all the plasma it can get at present and for the forseeable future hence it is unlikely that this hypothetical situation would arise.

31. To encourage any RTC to collect more plasma at present basically requires CBLA to offer them money. Since charging will generate no new money, only recycle that presently available this extra money would ultimately have to come from central funds. But if that money is available a charging mechanism is not required to target it. There could have been attraction in a charging system for plasma if it had been introduced at the outset of the plasma procurement programme. To change horses in mid-stream is unlikely to improve the provision of plasma to CBLA.

Policy changes in the funding of the NHS

32. Finally we consider whether the changes taking place elsewhere in funding of the NHS should or can be applied to the BTS. The idea is to give the money to the product or service user, and hence make the support service self-financing and responsive to the needs of the customer.

33. RTCs have a monopoly on the supply of blood etc to hospitals. Hospitals cannot go out to tender for the supply of blood. Therefore there can be no competition to stimulate efficiency at the RTCs. Hospitals will have to pay the price quoted or go without. In these circumstances placing the money in the hands of the customer is not therefore giving them the ability to influence the products they receive or the way the service is organised. This is one of the key objectives of making support services self-financing.

34. Additionally for RTCs to be completely financially self-supporting they would need to charge for their diagnostic tests, such as ante-natal testing and tissue typing, as well as the supply of reagents etc. The same is true of the reference work and provision of reagents currently carried out by CBLA.

35. On balance we do not feel that the introduction of charging systems will of itself increase the efficiency of the BTS or resolve the problems we have identified in chapter 11 of the report. One of the attractions of charging systems is the management information that they could provide but in our view such information is necessary before charging systems could be produced (hence our recommendation at chapter 9) and having produced the information it then becomes a policy matter as to whether it is considered necessary to instigate charging. We conclude that there are difficulties in introducing a comprehensive charging system however none of these is insuperable should the will exist for change. In chapter 11 of the report we produce a range of organisational options for change: a charging system, should it be considered desirable or necessary could be integrated into any of the options.

TABLE 1
(see page 6)

TOTAL AND PER CAPITA REGIONAL EXPENDITURE ON THE BLOOD TRANSFUSION SERVICE IN 1985/86

REGION	EXPENDITURE 1985/86 (£)	CATCHMENT POPULATION (millions)	PER CAPITA EXPENDITURE (£)
A	2,387,895	1.96	1.22
B	3,367,865	2.80	1.20
C	3,360,510	3.10	1.08
D	6,308,677	4.35	1.45
E	2,886,136	2.50	1.15
F	4,133,685	3.40	1.22
G	3,845,719	3.40	1.13
H	5,064,558	3.40	1.49
I	7,050,359	6.70	1.05
J	4,754,860	4.70	1.01
K	2,668,373	2.20	1.21
L	2,679,034	2.30	1.16
M	5,034,322	5.20	.97
N	4,206,631	3.20	1.31
TOTAL	57,748,624	49.21	1.17

Expenditure obtained from Cost Form 60 returns. Catchment populations obtained from questionnaires completed by RTCs.

TABLE 2
(see page 8)

NUMBER OF STAFF EMPLOYED IN EACH REGIONAL TRANSFUSION SERVICE

REGION	MEDICAL	SCIENTIFIC & TECHNICAL	NURSING & DAS*	ADMIN & CLERICAL	ANCILLARY	TOTAL	DONATIONS	DONATIONS PER STAFF MEMBER
A	5.7	56.7	105.0	61.8	59.6	288.8	182004	630
B	3.0	73.0	109.0	62.5	53.5	301.0	197066	655
C	6.1	86.4	86.0	77.0	60.0	315.4	156223	494
D	3.0	49.8	69.3	50.7	54.7	227.4	119190	524
E	5.7	50.9	64.5	44.6	34.7	200.4	106693	532
F	2.0	57.4	56.0	45.5	31.3	192.2	91084	474
G	6.0	45.0	43.9	37.6	25.9	158.4	91600	578
H	4.0	57.0	45.0	43.5	34.3	183.8	86276	470
I	3.3	71.6	85.8	48.0	46.3	254.9	136834	537
J	6.3	82.5	132.0	118.2	48.6	387.6	258513	667
K	4.0	57.0	109.5	53.2	57.8	281.5	138020	490
L	6.8	98.5	115.6	99.3	83.8	404.0	172800	428
M	5.0	53.0	94.0	62.0	52.0	266.0	155026	583
N	2.7	71.0	67.0	55.0	37.0	232.7	129326	556
TOTAL	63.7	909.6	1182.6	858.9	679.3	3694.1	2020655	547

* Donor Attendants

All figures are for the 1985/86 financial year. Staff numbers are shown in whole time equivalents and represent agreed complements, not staff in post. Medical staffing figures represent, as far as we are able to determine, the doctors employed at the RTCs - Senior Registrars on rotation and sessional medical officers are excluded. North Western region is shown on one line as are South West and South East Thames. The final colomn shows the number of donations dealt with per member of staff for each region in 1985/86. It is thus a very crude indicator of efficiency in staff usage terms.

TABLE 4
(see page 13)

ANALYSIS OF DONOR RESPONSE AND REJECTION RATES AND DONATIONS COLLECTED IN 1985/86

Region	Donors attending as a percentage of those invited			Donors rejected as a percentage of those attending			Donations obtained as a percentage of donors bled
	Ind	GP	All	Ind	GP	All	All
A						8.60	92.24
B			52.12			4.68	97.48
C	99.57	42.52	56.26	7.10	10.41	9.00	98.39
D	66.03	58.61	60.03	6.87	7.20	7.13	99.10
E	53.52	60.38	57.87	13.26	11.73	12.25	
F	54.04	47.51	47.82	2.91	3.82	3.77	91.01
G		34.13		4.74	8.84	6.98	98.02
H	66.49	61.85	62.87	9.27	11.35	10.86	96.92
I		49.56		7.78	8.91	8.60	97.72
J	63.11	59.51	59.97	8.96	7.79	7.95	97.80
K	94.20	38.08	48.42	13.57	13.77	13.70	98.10
L		27.84		11.92	13.41	13.16	90.84
M		46.38		15.14	11.61	12.26	
N	97.86	37.59	44.60	9.16	9.60	9.49	95.23

Ind = Industrial session

GP = General public session

Data obtained from questionnaires completed by RTCs. Blanks in the table indicate that the information required was not available.

TABLE 5
(see page 14)

DONOR RECRUITMENT AND LOSSES IN 1985/86

REGION	Estimated size of donor panel	Donors recruited	Donors lost	Donors transferred: In	Donors transferred: Out	Net gain (loss)	Percentage gain (loss)
A	81,953	8,296		7,157			
B	132,000	18,388					
C	127,287	11,956	15,760	*	1,343	(5,147)	(4.04)
D	316,000	39,489	23,739		3,000	12,750	4.03
E	129,000	12,863	9,362			3,501	2.71
F	200,000	15,339	13,226	3,039	1,637	3,515	1.76
G	210,000	25,000	21,000	1,500	1,600	3,900	1.86
H	192,875	28,356	35,051	10,462	3,458	309	0.16
I	322,000	42,615	34,576	7,426	923	14,542	4.52
J	152,190	24,558	23,772	3,080	2,698	1,168	0.77
K	98,539	13,944	13,508	*	1,232	(796)	(0.81)
L	95,000	13,437	13,074	*	*	363	0.38
M	169,714	18,315	31,606	2,080	3,640	(14,851)	(8.75)
N	100,000	19,375					
TOTAL	2,326,558	291,931	234,674	34,744	19,531	57,257	2.46

Donors transferred indicates donors transferred between regions. Not all regions keep these figures and where they are not available the colomn has been left blank. Other regions include transferred donors in their recruited/lost figures - this is indicated by an asterisk. The figures for net gains (losses) of donors include transfers for the regional figures but not in the total figure since there is no overall gain or loss of donors in England and Wales as a result of donors moving around the country. The total figures should be treated with caution given the incompleteness of the data.

TABLE 3
(see page 11)

ANALYSIS OF DONOR SESSIONS 1985/86

Region	Number of sessions held:				Average number of:	
	Ind	GP	Total	% Ind	donors bled per session	donations per session
A	500	1159	1659	30.1%	101	93
B			1753		76	74
C	673	703	1376	48.9%	134	132
D	359	1291	1650	21.8%	121	119
E	344	582	926	37.1%	98	
F	55	812	867	6.3%	198	180
G	637	973	1610	39.6%	76	74
H	239	784	1023	23.4%	108	104
I	287	623	910	31.5%	103	101
J	96	524	605	15.5%	142	139
K	533	980	1513	35.2%	92	90
L	373	1650	2023	18.4%	117	106
M	293	1211	1504	19.5%	92	
N	429	1198	1628	26.4%	111	106
Total	4818	12491	19062	27.8%	99	92

Ind = Industrial session

GP = General public session

Data obtained from questionnaires completed by RTCs. Blanks indicate that relevant data was not available.

TABLE 6
(see page 17)

ANALYSIS OF BLOOD COLLECTION TEAM COMPOSITION AND DONOR THROUGHPUT

Team member	Region A	B	C	D	E	F	G	H	I	J	K	L	M	N
Team leader	1	2	1	1	1	1	1	1	1	1	1	1	1	1
Donor attendant	9	9	11	7	7	9	7	9	9	6/7	12	11/12	9/11	7/9
Driver	2		2	1	1			1			1/2	2	2	
Driver/Heamoglobinist					1	1	1		1	1				
Driver/Clerk		2		1		1		1						1
Driver/special duties							1		1					1
Clerk	2		1		1		1			1	2	2	2	
Orderly	1							1		1				
JMLSO														
Total	15	13	15	10	11	12	11	13	12	10/11	16/17	16/17	14/16	10/12
Average number of donors per session	79	147	130	112	81	120	113	107	102	111	190	113/155	155	135
Donors dealt with per team member per session	5.3	11.3	8.7	11.2	7.4	10.0	10.3	8.2	8.5	11.1/ 10.1	11.9/ 10.6	7.1/ 9.1	11.1/ 9.7	13.5/ 11.3

Data obtained from questionnaires completed by RTCs. Where team membership is variable the range is indicated.

TABLE 7
(see page 32)

ANALYSIS OF REGIONAL TRANSFUSION CENTRE BUDGETS

Region	Total budget	Collection costs	Grouping costs	Processing costs	Distribution costs	Technical services costs
	£	£	£	£	£	£
A	4,133,685	2,469,768	209,810	528,721	148,296	777,090
	100%	59.75%	5.08%	12.79%	3.59%	18.80%
B	3,360,510	1,708,343	327,340	163,670	249,281	911,876
	100%	50.84%	9.74%	4.87%	7.42%	27.14%
C	5,064,558	3,713,900	469,243	492,705	177,552	211,159
	100%	73.33%	9.27%	9.73%	3.51%	4.17%
D	2,668,373	1,157,895	334,044	374,885	125,943	675,606
	100%	43.39%	12.52%	14.05%	4.72%	25.32%
E	5,034,322	2,597,503	444,349	954,354	412,200	625,916
	100%	51.60%	8.83%	18.96%	8.19%	12.43%
F	3,367,865	2,170,930	431,002	316,693	205,630	243,610
	100%	64.46%	12.80%	9.40%	6.11%	7.23%
G	4,754,860	2,060,119	176,118	295,878	218,814	2,003,931
	100%	43.33%	3.70%	6.22%	4.60%	42.14%
H	2,679,034	1,266,692	182,546	290,933	86,347	852,516
	100%	47.28%	6.81%	10.86%	3.22%	31.82%
I	2,886,136	1,585,208	265,334	232,587	196,528	606,479
	100%	54.92%	9.19%	8.06%	6.81%	21.01%
J	2,387,895	1,007,808	308,249	186,572	135,360	749,906
	100%	42.20%	12.91%	7.81%	5.67%	31.40%
K	3,845,719	2,409,813	468,177	354,539	116,499	496,691
	100%	62.66%	12.17%	9.22%	3.03%	12.92%
L	5,950,759	3,942,349	418,592	460,851	323,177	805,790
	100%	66.25%	7.03%	7.74%	5.43%	13.54%
M	4,206,631	2,800,702	254,883	382,325	80,537	688,184
	100%	66.58%	6.06%	9.09%	1.91%	16.36%
N	6,308,677	3,254,414	415,767	399,204	221,188	2,018,104
	100%	51.59%	6.59%	6.33%	3.51%	31.99%
Total	56,649,024	32,145,451	4,705,455	5,433,918	2,697,353	11,666,861
	100%	56.74%	8.31%	9.59%	4.76%	20.59%

Data derived from Cost Form 60 returns. The percentage figures represent the portion of each regions budget spent on the five defined areas of activity. As noted in the text there was considerable variation in region's interpretation of what costs should be allocated under each heading.

TABLE 8
(see page 32)

ANALYSIS OF DONATION COSTS 1985/86

Region	Total cost per donation	Collection cost per donation	Grouping cost per donation	Processing cost per donation	Distribution cost per donation	Technical services cost per donation	Cost per donation excluding technical services
	£	£	£	£	£	£	£
A	26.66	15.93	1.35	3.41	0.96	5.01	21.65
B	25.98	13.21	2.53	1.27	1.93	7.05	18.93
C	27.83	20.41	2.58	2.71	0.98	1.16	26.67
D	29.30	12.71	3.67	4.12	1.38	7.42	21.88
E	25.55	13.18	2.25	4.84	2.09	3.18	22.37
F	28.26	18.21	3.62	2.66	1.73	2.04	26.21
G	30.44	13.19	1.13	1.89	1.40	12.83	17.61
H	29.25	13.83	1.99	3.18	0.94	9.31	19.94
I	27.05	14.86	2.49	2.18	1.84	5.68	21.37
J	27.68	11.68	3.57	2.16	1.57	8.69	18.99
K	28.10	17.61	3.42	2.59	0.85	3.63	24.48
L	27.63	18.31	1.94	2.14	1.50	3.74	23.89
M	30.48	20.29	1.85	2.77	0.58	4.99	25.49
N	36.51	18.83	2.41	2.31	1.28	11.68	24.83
Average	28.62	15.88	2.49	2.73	1.36	6.17	22.45

Data obtained from Cost Form 60 returns.

TABLE 9
(see page 49)

COST PER ITEM OF RED CELL PRODUCTS 1985/86

Region	Whole Blood (£)	PWB (£)	FB (£)	SWB (£)	PRB (£)	CRC (£)	SAG[M] RC (£)	Buffy coats (£)	LPRC (£)	FRC (£)	RCB (£)
A*	16.88	16.88	19.96		9.62	10.08	10.29	10.90		13.79	17.43
B	14.57				9.27		9.41	9.87	10.33		16.11
C	19.78	19.78	22.94	22.94	12.26	12.29	12.46	13.09	13.89	16.07	23.55
D	15.36					10.79	11.01	11.79	12.80		23.45
E	16.23			23.46	11.64	11.72	12.11	13.53	15.37	20.35	
F	24.99				13.77	13.81	14.02		15.77		27.14
G**	15.00			17.00		(9.00)		10.00	10.00		
H	15.95	15.95	20.15	20.15	10.37		10.64	11.47	12.54		22.46
I	19.49	19.49	22.69		12.18		12.39	13.02		16.05	23.23
J	15.99			13.40	10.76	10.97		12.31	12.61		18.89
K	22.18		24.61	24.60	11.89		12.04	12.52		14.83	21.27
L	15.04		20.90	20.90			10.19	11.66	13.16		
M**	20.55		25.06	25.04		(12.89)				18.17	
N	17.59	17.59	20.36		9.69		9.87		11.11		20.09
AVERAGE	17.83	17.94	22.08	20.94	11.15	11.24	11.31	11.83	12.76	16.54	21.36

PWB = Paediatric whole blood
FB = Filtered blood
SWB = Saline washed blood

PRB = Plasma reduced blood
CRC = Concentrated red cells
SAG(M) RC = SAG(M) red cells

LPRC = Leucocyte poor red cells
FRC = Frozen red cells
RCB = Red cell compatible blood

Data obtained from Cost Form 60 returns. Blanks indicate that a region does not produce the product in question.

* This region also produces a small amount of PRB at £10.09 per unit and platelet reduced blood at the same cost.

** These regions did not calculate the cost of CRC and SAG(M) seperately.

TABLE 10
(see page 49)

COST PER ITEM OF NON-RED CELL PRODUCTS 1985/86

Region	Platelets (£)	PRP (£)	Cryo. (£)	FFP H (£)	Paed. FFP (£)	FFP F (£)	SAG[M] FFP (£)	Cryo-super (£)	TEP (£)
A	9.61	8.81	6.90	9.01	6.42	6.75	9.41	7.21	1.26
B	7.18	6.63	5.12	6.78		7.05	7.00	5.32	12.72
C	10.42		7.46	9.80	6.97	10.22			1.36
D	8.26		6.11	7.48		8.00	7.90	6.51	1.63
E	11.23		8.65	9.82		10.76	10.58	9.37	16.67
F	11.90		8.56	11.14			11.56	8.95	
G*	8.00	8.00	6.00	8.00		(8.00)			1.00
H	9.43		6.91	8.61	6.27	9.16	9.06		1.73
I	10.25		7.35	9.62		10.04	9.96		1.31
J	8.05	7.22	7.91	7.41		7.84			1.34
K	9.60		6.79	9.12	6.85	9.44	9.38		1.00
L	10.29		7.76	9.14		9.90			15.87
M*	11.96		8.70	11.07		(11.56)			1.85
N	8.88		6.36	8.35		8.70	8.64		1.12
AVERAGE	9.65	7.67	7.18	8.95	6.63	9.03	9.28	7.47	4.53

PRP = Platelet rich plasma
Cryo. = Cryoprecipitate
FFP CU = Fresh frozen plasma (FFP) for clinical use
Paed. FFP = Paediatric FFP

FFP F = FFP for fractionation
SAG(M) FFP = SAG(M) FFP for fractionation
Cryo-super = Cryosupernatent
TEP = Time expired plasma

Data obtained from Cost Form 60 returns. Blanks indicate that a region does not produce the product in question.

* These regions did not calculate the cost of FFP and SAG(M) FFP for fractionation seperately.

TABLE 11
(see page 49)

NUMBER OF UNITS OF RED CELL PRODUCTS MADE IN 1985/86

Region	Whole Blood	PWB	FB	SWB	PRB	CRC	SAG[M] RC	Buffy coats	LPRC	FRC	RCB
A*	29315	580	202		30729	175	68658	1449		136	5837
B	74733				47589		2029	97	280		3910
C	76750	285	1477	141	35606	22241	38070	1050	282	355	2382
D	18108					59435	14482	2397	80		128
E	81311			74	9739	39676	58082	2093	1870	182	
F	39960				51315	9685	7638		813		850
G	51432			34		31216	63920	546	2184		
H	39533	164	73	65	11946		37759	48	48		306
I	41858	1920	316		17054		34402	24		14	1069
J	39830			25	29	41761		13	805		1374
K	19303		5138	5	28821		81720	435		88	8004
L	123330		1343	169	10544		135660	68442	332		
M	63483		1254	23		48030	18500			30	
N	94593	218	28		56343		26440		807		1650
AVERAGE	793539	3167	9831	536	299715	252219	587360	76594	7501	805	25510

PWB = Paediatric whole blood
FB = Filtered blood
SWB = Saline washed blood

PRB = Plasma reduced blood
CRC = Concentrated red cells
SAG(M) RC = SAG(M) red cells

LPRC = Leucocyte poor red cells
FRC = Frozen red cells
RCB = Red cell compatible blood

Data obtained from Cost Form 60 returns. Blanks indicate that a region does not produce the product in question.

* This region also produces 32,000 per units of platelet reduced blood.

TABLE 12
(see page 49)

NUMBER OF UNITS OF NON-RED CELL PRODUCTS MADE IN 1985/86

Region	Plat-lets	PRP	Cryo.	FFP H	Paed. FFP	FFP F	SAG[M] FFP	Cryo-super	TEP
A	37409	2937	3396	9903	588	17724	71126	3396	15707
B	20762	46	5342	12631		30033	2029	5342	24694
C	76400		7335	22050	707	41365	38070		7765
D	26462		8294	5806		43510	15670	9809	5042
E	38279		4694	14364		30542	58082	3911	6238
F	24494		3613	7203		60490	7638	2681	
G	32930	16	6947	7494		30116	63920		22516
H	11851		3827	5871	218	5891	37759		8225
I	16838		169	5176		13214	34582		9096
J	16370	203	1020	5177		35384			8987
K	23661		2128	10047		10839	81720		5856
L	73399		9779	23514	161	2326	122765	4002	8545
M	23026		4566	10417		37613	18500		13352
N	29584		19321	10443		65852	26440		18099
AVERAGE	451465	3202	80431	150096	1674	424899	578301	29141	154950

PRP = Platelet rich plasma
Cryo. = Cryoprecipitate
FFP CU = Fresh frozen plasma (FFP) for clinical use
Paed. FFP = Paediatric FFP

FFP F = FFP for fractionation
SAG(M) FFP = SAG(M) FFP for fractionation
Cryo-super = Cryosupernatent
TEP = Time expired plasma

Data obtained from Cost Form 60 returns. Blanks indicate that a region does not produce the product in question.

TABLE 13
(see page 50)

ANALYSIS OF MAJOR RED CELL PRODUCTS ISSUED IN 1985/86

Region	Percentage of Red cell products issued as: Whole blood	PRB/CRC	SAG(M)
A	18	39	43
B	60	38	2
C	44	34	22
D	20	65	16
E	43	26	31
F	37	56	7
G	35	21	44
H	44	13	42
I	45	18	37
J	49	51	0
K	15	22	63
L	46	4	50
M	49	37	14
N	53	32	15
Average	41	27	31

Data obtained from Cost Form 60 returns made by Regions and questionnaires completed by RTCs.

TABLE 14
(see page 64)

NUMBER OF DONORS BLED (1982 - 1985)

Region	1982	1983	1984	1985
A	134392	133039	131947	133544
B	143626	152874	154905	149128
C	162229	166362	174425	169680
D	84629	86275	87650	86393
E	180644	183033	189246	190048
F	145472	145241	136647	138875
G	256589	301029	302097	282738
H	90030	93889	95719	94088
I	115997	118822	119689	111129
J	172462	171678	170859	168169
K	195332	193048	200128	199389
L	115478	119604	117589	121642
M	179351	179844	181638	180133
N	82763	91102	96087	94104
TOTAL	2058994	2135840	2158626	2119060

PERCENTAGE CHANGE COMPARED TO 1982

Region	1983	1984	1985
A	-1.01	-1.82	-0.63
B	6.44	7.85	3.83
C	2.55	7.52	4.59
D	1.94	3.57	2.08
E	1.32	4.76	5.21
F	-0.16	-6.07	-4.53
G	17.32	17.74	10.19
H	4.29	6.32	4.51
I	2.44	3.18	-4.20
J	-0.45	-0.93	-2.49
K	-1.17	2.46	2.08
L	3.57	1.83	5.34
M	0.27	1.28	0.44
N	10.08	16.10	13.70
TOTAL	3.73	4.84	2.92

Figures derived from NBTS47 returns.

TABLE 15
(see page 64)

MAJOR BLOOD MOVEMENTS 1985 - 1986

Region	Imports	Exports
A		1575
B		6000
C	11000	
D	30000	
E		1460
F		5175
G		2560
H		2250
I		2500
Scotland		20000
TOTAL	41000	41520

Only exports/imports in excess of 1000 units per annum have been included.

TABLE 16
(see page 65)

NUMBERS OF PLATELET ISSUES (1982 - 1985)

Region	1982	1983	1984	1985
A	14394	12914	15484	21031
B	24871	21701	25665	24385
C	15116	21007	25082	31339
D	14978	14790	15463	16028
E	65758	74565	77497	78934
F	20578	21116	25220	27413
G	56428	66620	69392	73249
H	8139	10332	11695	11443
I	11840	13731	16153	16499
J	18473	22201	24447	44919
K	21475	26938	31883	35617
L	18720	19448	20668	24245
M	23492	22355	26393	32683
N	14566	16556	18547	24568
TOTAL	328828	364274	403589	462353

PERCENTAGE CHANGE COMPARED TO 1982

Region	1983	1984	1985
A	-10.28	7.57	46.11
B	-12.75	3.19	- 1.95
C	38.97	65.93	107.32
D	- 1.26	3.24	7.01
E	13.39	17.85	20.04
F	2.61	22.56	33.22
G	18.06	22.97	29.81
H	26.94	43.69	40.59
I	15.97	36.43	39.35
J	20.18	32.34	143.16
K	25.44	48.47	65.85
L	3.89	10.41	29.51
M	- 4.84	12.35	39.12
N	13.66	27.33	68.67
TOTAL	10.78	22.74	40.61

Figures derived from NBTS47 returns.

TABLE 17
(see page 68)

NUMBER OF DONORS PER THOUSAND HEAD OF POPULATION - 1985

Region	Catchment Population (Millions)	Donors Bled	Donors per Thousand
A	5.0	169680	33.94
B	5.2	199389	38.34
C	4.6	180133	39.16
D	3.4	138875	40.85
E	2.3	94088	40.91
F	2.2	94104	42.77
G	3.1	133544	43.08
H	2.8	121642	43.44
I	6.5	282738	43.50
J	1.9	86393	45.47
K	3.2	149128	46.60
L	2.3	111129	48.32
M	3.4	168169	49.46
N	3.4	190048	55.90
TOTAL	49.3	2119060	42.98

Figures derived from NBTS47 returns.

TABLE 18
(see page 71)

TOTAL RED CELL ISSUES AND RETURNS (1985) WITH PERCENTAGE RETURN RATES

Region	ISSUES		RETURNS		% RETURN RATE	
	NHS	Non-NHS	NHS	Non-NHS	NHS	Non-NHS
A	122063	1722	23837	991	19.53	57.55
B	115836	1589	13476	654	11.63	41.16
C	140472		4773		3.40	
D	77147	1758	9645	730	12.50	41.52
E	164337	21512	5680	716	3.46	3.33
F	123767		5085		4.11	
G	246999	13885	10007	2734	4.05	19.69
H	78445	2333	7838	1179	9.99	50.54
I	79986		4945		6.18	
J	134225	4032	10413	1623	7.76	40.25
K	175547	4431	10751	1041	6.12	23.49
L	109268		11054		10.12	
M	141282	3065	8275	217	5.86	7.08
N	79868		6442		8.07	
TOTAL	1789242	54327	137043	5063	7.66	9.32

Figures derived from NBTS47 returns. A number of regions do not keep records of non-NHS returns. Accordingly, there are no entries in the non-NHS columns for these regions.

TABLE 19
(see page 80)

ANALYSIS OF PLASMA COLLECTION

Region	Percentage of donations harvested for plasma	Percentage of plasma collected by the SAG(M) method	Number of ordinary donations collected for each plasmapheresis donation
A	64	46	
B	35	2	
C	56	21	22
D	71	17	27
E	52	29	289
F	57	6	31
G	65	41	92
H	54	41	416
I	50	32	52
J	47	0	43
K	75	60	173
L	65	57	48
M	48	13	12
N	59	15	48
Average	58	29	47

Data obtained from Cost Form 60 returns made by Regions and questionnaires completed by RTCs. Blanks indicate information not obtained.