

Blood Matters

Quarterly information for hospitals served by the National Blood Service

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Introduction

Welcome to the second national issue of Blood Matters. From the National Blood Service point of view it is proving to be an excellent means of communicating with all our 'user' hospitals. To be able to use one channel of communication to update everybody about 'matters of mutual interest' rather than having to resort to multiple individual mailshots, is much more satisfactory and hopefully the feeling is mutual.

In this issue the progress being made in two collaborative ventures with hospitals is reported; the aim of one, the EDI Project, is to facilitate and improve two way communications between hospitals and Blood Centres whilst the aim of the other, the Blood Stocks Project, is to improve the physical management of blood stocks and effectiveness of the whole supply chain. Both projects have demonstrably improved relationships between hospitals and Blood Centres; as to succeed they have to be based on trust and mutual co-operation. There is increasing recognition that voluntary donated blood is a limited and expensive resource, so it is in everyone's best interest to maximise usage and minimise wastage.

Adequate provision of Group O RhD negative blood to meet current demand is a case in point, and the background to this problem together with proposed national guidelines are reported in this issue. In view of the recent controversy surrounding the use of albumin, it was also thought appropriate to include a short report on the CSM review of the therapeutic role of albumin.

As 'D' day approaches for the implementation of NAT testing as a release criteria for frozen blood components for transfusions and for universal leucodepletion, update progress reports on these two topics are also included.

Finally BPL's award for its Communication Strategy makes interesting reading as it explains how BPL managed the transition from UK plasma to US plasma in very difficult circumstances.

I hope that you will find this second issue informative and helpful, but please do not hesitate to contact my colleague Alison Murray on 01923 486800, fax 01923 486801 or email angela.robinson@nbs.nhs.uk if you have any comments or ideas about this newsletter.

Dr Angela Robinson
Medical Director, National Blood Authority
Visit our website at www.bloodnet.nbs.nhs.uk

National Blood Stocks Update

INTRODUCTION

Welcome to the third update of the National Blood Stocks Project. Whereas before the two previous updates were issued as separate newsletters, the project group has decided that Blood Matters will be the ideal vehicle for keeping everyone updated in the future. I hope that these regular updates will keep key hospital staff aware of the developments that are being made in this exciting project.

Terry Male
Project Director

Project Background and Objectives

In January 1998, the National Blood Stocks project was set up. Its membership includes hospital and National Blood Service (NBS) representation.

The project's objectives are to:

- improve the effectiveness of the management and use of the blood supply by way of a series of local collaborative projects with hospitals designed to understand the factors that influence supply and demand;
- produce and implement locally, recommendations for improvement. (The quantified results from the local projects, based on change implementation experience, will be used to provide the basis for nationally applicable recommendations for change.)

Following an initial pilot data collection study, the first phase of the project consisted of a three month study conducted with 22 volunteer hospitals, as well as every blood centre in the NBS. The result of this exercise was the quantifying of;

- stockholding levels
- request and issue practices
- wastage rates

Also quantified - and probably for the first time ever was the impact that low stock levels have on blood centres and hospitals - especially in how this relates to the latter in terms of failure to supply requested blood orders.

Stockholding Data

WHAT IS AN IDEAL STOCK LEVEL

The data collected thus far shows significant differences in the stockholding approaches that are adopted by both hospitals and blood centres.

For example, blood centres have a stated ideal stock level for O positive as being between 2.5 and 3.0 days. Yet during the period measured, this figure ranged in practice from just 0.8 days to 2.4. When these actual stock level figures were translated into the impact that they had on hospitals using a range of I-3, with 3 the highest impact the average was 1.06. Yet this masked considerable differences between different parts of the country, with some centres recording impact scores of 2 and 3.

Hospitals on the other hand tended to have a higher and broader range of ideal stock levels, with figures ranging from 2.8 to 11.8 days for O positive. Over the period measured, hospitals tended to match their respective preferred levels fairly closely. These appear to have been maintained largely irrespective of the position at their supplying blood centres.

Clearly there are significant variations in stockholding practice across the country that merit further investigation.

THE IMPACT OF CUTTING ORDERS

Another finding worthy of note, was the impact that cutting orders during times of extreme pressures on O positive stocks had on hospitals and blood centres alike. Performance comparisons demonstrated clearly that when orders are cut, hospitals compensate by increasing the amount that they request blood centres to deliver. The work also proved that where the policy of cutting orders is reversed, requests for blood from hospitals fall back to more realistic levels.

Therefore, the practice of cutting orders has little or no impact on the amount of blood issued. It does, however, have significant consequences for both hospitals and blood centres in terms of increased stress on everyone involved in the blood supply chain.

BLOOD WASTAGE

The first phase of the project also collected daily wastage data. When extrapolated to cover all 12 blood centres and 350 hospitals for a whole year, up to 6,000 and 60,000 units of blood respectively could be lost from the supply chain.

Given the understandable collection and production constraints under which blood is processed at blood centres, along with the varying conditions in how it is used at hospitals, it is unrealistic to expect to achieve zero wastage levels. Yet lessons can be learnt that will help reduce wastage significantly, thus saving a valuable and hard pressed resource.

- time expiry is the major cause for all blood groups at both blood centres and hospitals;
- at hospitals, significant wastage is due to lack of temperature control outside the hospital transfusion laboratory an area over which transfusion staff have little or no control;
- a sizeable number of wasted units are group AB.

SO WHERE NEXT?

Two major themes have now emerged from the initial work of the project:

- continual improvement in the relationship between hospitals and blood centres, based on trust and mutual co-operation;
- improvement in the physical management of blood stocks and effectiveness of the whole supply chain.
- The development of both of these areas is seen as essential to the long-term success of an optimal demand/supply relationship between blood centres and hospitals.

The Hospital Experience

All of the project's hospital participants have expressed a desire to continue with this important work. This exceptional and highly encouraging level of commitment is

further underlined when the amount of reporting, which is produced manually on a daily basis, is taken into consideration.

One such enthusiast for the National Blood Stocks project is the Kent & Sussex Weald NHS Trust, which is based at Tunbridge Wells in Kent. Chief MLSO Bob Slater, heads up its blood transfusion laboratory located at the nearby Pembury Hospital.

"Our trust consists of three main hospitals and like all such multi-sites, keeping track of requests for blood and where it goes is a problem," comments Bob. "It is even worse in our case, because the main surgery, A&E and intensive care units are based at Tunbridge Wells and our transfusion laboratory is three miles away in Pembury."

Bob and his team agreed to become involved in the pilot work out of interest, as well as to see if they could learn anything that could help them cope better with their heavy workload.

Turning to what he and his colleagues have learnt from the taking part in the project, Bob commented: "One area over which we now have a much better understanding is our use of O negative blood. At Kent & Sussex Weald, we have 10 units of O neg 'flying squad' blood distributed between three sites. Through the pilot, we now have a clearer idea of how this scarce resource is being used."

Bob went on to say that: "We also got involved in a case study on the use of AB positive blood. For some time now, our local blood centre at South Thames has been sending us four units of AB positive every week. When we analysed its use, I was surprised to see how little is returned. It was a valuable lesson for us and we are now considering whether such a policy should be extended for group B blood too."

Next Steps

The second and third phases of the project, which began in April 1999, will run for 12 months. They will develop benchmarks for blood stockholding procedures, which will then be used by hospitals and blood centres to assess continually their respective local practices.

These benchmarks will be refined for national use, following an in-depth investigation of the impact that changing practices have on hospitals. They will then form the basis for the development of new national guidance that will help ensure that best practice is adopted throughout all points of the blood supply chain around the country.

THE NEED FOR CONSENSUS

While the project has benefited enormously from the collaborative approach that has been adopted by hospitals and blood centres, there is now a need to build a consensus across the wider NHS an issue that is now under active consideration. Options that are being reviewed include getting the formal involvement of the NHS Executive in Leeds and bringing the project under initiatives led by the Chief Medical Officer (CMO).

EARLY RESULTS

All of these developments will undoubtedly affect the scope, pace and eventual outcome of the overall project, yet results are already beginning to come through. Following an initial analysis of the data from the second phase, significant differences in operational practice have been observed between the blood centres and hospitals for example shortage in the former and excess stocks in the latter, where hospitals are faced with having to use relatively short shelf-life stocks.

The NBS has also looked at its practice of cutting hospital orders during times of stock pressures, especially for group O. The data clearly shows that it leads to inflated orders, thus distorting real, i.e. patient, demand. It is this realisation that has led to the development of new stock management policies that will help to prevent the need for order cutting during future periods of low stock levels.

In conclusion, the NBA Executive is giving the project the highest priority because its success is the key to establishing total collaboration between hospitals and blood centres. This in turn is fundamental to putting into place the optimal blood supply relationship.

USEFUL CONTACTS

Anyone requiring more information should contact his or her respective representatives on the project group:

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NBS National Blood Stocks Project
September 1999

Proposed Guidelines For The Use Of Group O RhD Negative Red Cells

BACKGROUND

Every blood service encounters recurrent short-falls of O RhD negative red cells and the NBS is no exception. Nationally, during 1998/99, hospital orders for this group

were cut on 48 out of the 52 weeks and there was an overall deficit of 796 O RhD negative red cells (demand 240,181 and issues 223,838). To a limited extent, this is predictable, given that O RhD negative red cells are justifiably given to some non-O RhD negative recipients, for example in emergencies before the patient's group is known, or following an ABO incompatible stem cell transplant.

The NBS always strives to increase collections of O RhD negative cells. Between 6.7 and 8.3% of the UK population is O RhD negative and this figure depends upon geographical location, ethnic mix and which source is used to calculate the proportion of RhD negative! However, the NBS with specific targeting of O RhD negative donors has increased its collection of this group to 9.7% in 1998/99 and so far in 1999/2000 to 9.95%. However, unfortunately this is not enough, and demand continues to exceed supply and is currently 10.08%.

82% of blood banks supplied by the NBS request more than 8% O RhD negative red cells. The consequences of overstocking O RhD negative are seen in repeated audits across the country, which have shown that the most common reasons for O RhD negative units being transfused to non-O RhD negative recipients are to prevent time expiry of units, or because the hospital does not routinely stock B negative red cells.

The NBS has built an O RhD negative donor base greater than the percentage naturally occurring in the population, but current demand levels mean that we have to work these donors extremely hard to keep pace. Any further enhancements of O RhD negative collections would be both difficult and costly. If every sizeable hospital stocked approximately 8% O RhD negative red cells, then the balance of supply and demand would be maintained and it would also allow reserves for neonatal or complex phenotype units.

The NBS Transfusion Medicine Clinical Policies Group has drawn up a guideline which is given below. This stresses the importance of hospital stock levels for group O RhD neg. It also gives our support, in certain patient groups, for electively transfusing O RhD positive blood to O RhD negative recipients, other than pre-menopausal females. This step, however, would not be necessary if every hospital would be prudent with their O RhD negative requests and employ timely rotation of their emergency units. The Group has consulted with a small number of hospital Consultant Haematologists across the country, but we would really welcome everyone's comments on these guidelines, and any further suggestions you may have for keeping the group O RhD negative red cells in balance.

Comments should be forwarded to Dr Sue Knowles via your local Centre by the end of November.

The Guidelines

GENERAL PRINCIPLES

- It should not be necessary for hospitals to routinely stock more than 8% red cells as group O RhD negative (this is slightly higher than the proportion of the population that is group O RhD negative).

- Adequate stock management policies should be in place to minimise wastage of O RhD negative red cells arising from time expiry, and avoid the need to electively transfuse to non-O RhD negative recipients to prevent time expiry.
- Adequate stocks of other groups should be maintained by hospital blood banks to avoid the unnecessary use of group O RhD negative blood for patients of other groups.
- Sensitisation to RhD through blood transfusion must always be avoided in pre-menopausal women (< 60 yrs when unknown). These guidelines aim to ensure continuous supply for this patient group.
- Patients with a weak D status (D~) should be given RhD positive blood, and anti-D reagents should be selected so that all RhD positive patients, other than category Dvi are identified (see Guidelines for Pre-transfusion Compatibility Procedures in Blood Transfusion Laboratories, Transfusion Medicine 1996, Vol 6, p 273-283).

Mandatory Indications for use of O RhD Negative Blood

- O RhD negative patients with anti-D.
- O RhD negative pre-menopausal females.
- In emergency to pre-menopausal females of unknown blood group.

Recommended Indications for the use of O RhD Negative Blood

- O RhD negative patients who will receive repeated transfusions, or are likely to become transfusion dependent (e.g. haemoglobinopathies, aplastic anaemia, myelodysplasia).

Acceptable Indications for use of O RhD Negative Blood

- In an emergency situation, a maximum of two units of O RhD negative blood should be given while the patient's blood group is being established. A switch to group specific blood is safe, and should then be made.
- Infants less than one year, if group specific 'baby blood' is unavailable.
- If specific phenotyped blood provided is O RhD negative

Use of O RhD Positive Blood for O RhD Negative Patients

- **O RhD positive cells should be used in large volume blood replacement (e.g. more than eight units of blood) in females over the age of 60 and adult males in whom no anti-D is detectable.**

- It is acceptable (to electively give O RhD positive red cells to group O RhD negative female patients over the age of 60 years and adult males who have no anti-D detectable).

NBS Transfusion Medicine Clinical Policies Group September 1999

Electronic Data Interchange (EDI) Update

EDI is the process by which data is passed between information systems in standard electronic formats with the potential benefits that more information can be transferred with less errors at an increased speed and that paperwork can be reduced. EDI is widely used in industry and can be a pre-requisite for business to take place. The use of EDI between the NBS and hospitals has become a possibility now that all NBS centres use the national computer system, PULSE, which will greatly facilitate the transfer of information in a standard format.

Since September 1997 an NBS/NIBTS project has been evaluating EDI as a means of communicating the ever increasing volume and complexity of information passing between the NBS and hospitals. The following project objectives were set:

1. To identify and prioritise the information to be transferred.
2. To perform a technical evaluation of data delivery methods.
3. To make recommendations from the above, run pilot schemes and cost the implementation of such a system.

A multi-functional project team has been set up and has met with representatives from hospitals and from hospital computer system suppliers. Following a meeting with hospital representatives in February 1998, priorities for information transfer have been set with blood order and issue information at the top of the list, followed by reference services results and information.

In November 1998, a three month pilot study began with the Royal Brompton Hospital and this demonstrated it was possible to automatically transfer information on deliveries to a secure website in a nationally agreed file format, securely and accurately. Once downloaded from the website by the hospital, the data can be imported into an Access database for reporting and manipulation. This has provided a foundation for this information to be downloaded into hospital computer systems which will provide most benefit to hospital blood banks.

This summer three further hospitals (the Royal Cornwall Hospital, Truro, John Radcliffe Hospital, Oxford and Dryburn Hospital, Durham) have been added to the pilot. Enhancements to the functionality of PULSE are currently being tested before these pilots can be extended.

NBS/NIBTS EDI Project Group September 1999

The Therapeutic role Of Albumin Defined

The therapeutic role of albumin has recently been revised by the Committee for Safety of Medicines (CSM) following a report to them from an Expert Working Party (EWP) facilitated by the Medicines Control Agency (MCA) in the latter half of 1998. This EWP consisted of clinicians from several disciplines who have experience in managing adults and children with conditions for which, traditionally, albumin might be a considered part of their treatment. The recommendations of this EWP were consolidated into new texts for parts of the Summary of Product Characteristics (SPC), the prescribing information for the professions, and the Patient Information Leaflet (PIL), the useful advice for the public.

Albumin is now clearly seen as a replacement fluid for hypovolaemia, when an improvement in oncotic pressure is needed. The 20% solution of albumin is recommended when a relatively low salt infusion is additionally required. No specific clinical diagnoses are listed as the potential range is wide. However, the use of albumin simply to 'top up' a patient with low serum albumin, in the absence of hypovolaemia, has now been removed as an indication. The following short text replaces the previous detailed version under 'Therapeutic Indications':

"Restoration and maintenance of circulating blood volume where deficiency has been demonstrated and use of a colloid is appropriate" with an additional clause for 20% albumin "...and where electrolyte or fluid load is contra-indicated."

Changes to texts in later sections reinforce the fact that although albumin may be a 'natural' product, it can produce adverse effects if used inappropriately - in common with all therapeutic interventions. With albumin, the pathological state of the patient's cardiovascular system is the key determinant. The new SPC is strengthened in several places with regard to the potential for cardiovascular overload and hyperhydration, for example in the 'Monitoring' section:

"Hypervolaemia may occur if the dosage and rate of infusion are too high ...".

Excessive capillary permeability can allow abnormal distribution of albumin leading to end-organ damage, for example the section on 'Special Warnings' states:

"Special care should be taken when administering albumin in pathological states which affect capillary integrity."

Thus, emphasis is placed on careful monitoring of the patient. In most (reputable) clinical units, this activity will already be routine, but it is still a timely reminder to everyone to ensure full compliance with such procedures.

As a consequence of the importance of monitoring of the individual's clinical state and progress, no dosages are now specified, unlike the 'rule of thumb' previously presented in the SPC. The 'Posology' section states:

"The dose required depends on the size of the patient, the severity of trauma or illness and on continuing fluid and protein losses. Measures of circulating volume and not plasma albumin levels should be used to determine the dose required."

A new reminder when considering the dose for children is that plasma volume is related to bodyweight and not just age.

The message to clinicians is to monitor the patient carefully and give the requisite amount of albumin tailored for that patient to maintain the appropriate physiological status.

In summary, the conclusions from the EWP, substantiated by the CSM, are that albumin has a role in hypovolaemia with careful monitoring of the patient and the dosage adjusted in accordance with the measured response.

Dr Clive Dash, Medical Director, BPL September 1999

Leucodepletion Update

Work within the NBS to implement Universal Leucodepletion (LD) is now entering its final stage. This article, written in September 1999, is a general update on the status of the Project. It will also outline our plans to handle non-LD components (particularly FFP and Cryoprecipitate) in stock after 1st November.

The extent of LD

By the end of July 43.9% of red cells, 100% of platelets but none of the FFP or Cryoprecipitate produced by the NBS were issued LD. The proportion of platelets provided by Apheresis had risen to 40%. The percentage of LD red cells received by each Hospital depends on the readiness of the Blood Centre supplying it. No hospital is currently receiving less than 25% LD red cells, which is more than adequate to meet BCSH guidelines for prescription of LD components.

Clearly a considerable amount of work must take place in the remaining weeks to full implementation on 1st November. The situation is dictated by structural change to buildings. The processing systems that will be used are in place and either in use or ready. There is little room for the unforeseen but currently we are on track to meet the 1st November target. In its final phases as throughout, the Project will be guided by consideration of the overall clinical safety of the blood supply.

Building

Some Blood Centres have required extensive building work which is now either completed or ongoing at every site. There has been some slippage but every site is presently proceeding along a time-line compatible with a 1st November implementation date.

Equipment

The procurement process has proceeded to plan with regard to both the purchase of machinery and evaluation work to allow the NBS to put to tender the blood collection pack systems, which will be required for the first 12 months. Packs will be purchased from four manufacturers (Baxter, Pall, NPBI, Macopharma) in line with NBS policy not to be reliant on a single source of supply. Blood Services throughout the developed world are increasingly adopting a universal LD policy which might pose the risk that these sophisticated blood pack systems will be in short supply. The security of supply to the NBS in both quantity and quality has been assessed in detail with each manufacturer and we are confident that needs will be supplied.

Staff

This Project involves all NBS staff. New staff are being recruited, particularly into blood processing departments and apheresis units. There is also an impact on general blood collection, with both changes in procedures and more donations required as there is slightly more wastage with more complex processing procedures. The implementation process must be underpinned by a major training effort. Both recruitment and training are proceeding according to Project deadlines. The extraordinary effort particularly of colleagues working in collection and processing to adapt to leucodepletion and implement it to target deserves to be acknowledged.

Counting

As was outlined in the last edition of Blood Matters counting low numbers of leucocytes in blood components is not straightforward. It is time consuming and on certain machines technically complex. With present technology, quality control cannot be based on counting every component. Counting a proportion of components with statistical process control has to be adopted. Extensive developmental work has identified

the best protocol for the flow cytometers available in the NBS and operating procedures are in place and in use. Similarly IMAGN machines which use laser technology to count stained cells in a fixed capillary rather than in a flowing stream have been evaluated and brought into use so that an alternative technology is available.

A great deal has been learnt from quality assurance exercises run from a single laboratory within the Service. Both External Quality Assessment (EQA) and reproducible internal controls are important to getting counting right. EQA will eventually be run external to the Service and a pilot scheme has been set up by the United Kingdom National External Quality Assessment Schemes for Leucocyte Immunophenotyping which will issue first samples in September, then run for 12 months with the objective to achieving full NEQAS status thereafter. At the same time internal quality control samples that are sufficiently stable to be widely distributed are being developed. Getting the numbers correct is essential to statistical process control. This is being achieved. At the same time that process of control has been encapsulated in operating procedures and an extensive staff training programme is underway.

Contingency

What happens if a particular leucodepletion process fails to meet specification? The evaluation of systems requires they demonstrate capability (this is assessed statistically and links in with the statistical control process) which makes this unlikely. At this point in implementation we have considerable experience of the processes that we have selected and increasing confidence in their capability and of the process control approach that we have adopted. Nevertheless, it is important that contingency arrangements are in place for failure. Much effort has been invested in developing operating procedures for this. The availability of alternative systems helps considerably. Final details are not yet in place and a full account will be given in a later edition of Blood Matters.

Use of non-LD Blood Components after 1st November 1999

Dr Angela Robinson, NBS Medical Director has already written to indicate that the implication of the implementation date of 1st November is that all components leaving NBS processing lines on or after that date will have been through a leucodepleting process. With the exception of components for paediatric use (where LD is an established part of the specification) LD components state this on their labelling information and are easily distinguished from non-LD. It is likely that not all components in stock on 1st November will have been leucodepleted. Platelets are not a problem, since they have all been leucodepleted since the beginning of this year. It is possible that there will be some non-LD red cells in the system for up to five weeks after 1st November. Stocks, if any, should be small and dependant on the overall blood supply at the time. If stocks permit, we will remove non-LD red cells from our own stock. We do not plan to recall any non-LD red cells from hospitals.

Frozen components are more of a problem. In production their leucocyte content is lower by at least two Logs than red cells or platelets, even without further filtration. A clinical need for LD FFP or Cryoprecipitate has not been identified apart from the theoretical risk of vCJD. These frozen products are already regarded as CMV safe. Against this background we will facilitate the change to LD frozen components by keeping stocks as low as possible prior to the

implementation date and allowing stock to be replaced through natural usage. We accept that there may come a point when a formal withdrawal and exchange of stock held in hospital freezers for their LD equivalents will be needed. We are not yet able to fix such a date, but it will not be until after the millennium.

Clinical Research

One of the more attractive potential benefits of LD which is implied in many studies is that it will reduce the impact on patient's immune defences by the transfusion of allogeneic leucocytes. We have undertaken to study this by examining post-operative infection in surgical patients in nine hospitals as part of LD implementation within the NBS. The first six month phase of this study when data is collected from patients receiving non-LD components is close to completion. Similar data will be collected next year when all patients will receive LD components. This is an important Project. We will bring you up-to-date with its results through Blood Matters.

NBS Leucodepletion Project Implementation Board September 1999

NAT (Nucleic acid Amplification Technology) for Detecting HCV (Hepatitis C Virus) RNA in the NBS

In the first issue of Blood Matters we described the two phase approach of the NBS to the introduction of NAT for HCV RNA into the routine donor screening programme:

Phase 1

To provide HCV RNA negative fresh frozen components for direct clinical use.

Phase 2

To provide HCV RNA negative labile components (red cells and platelets).

PHASE 1

The testing of all donations was fully implemented earlier this year. Plasma from donor samples is made into 'minipools' (each consisting of aliquots from 96 donor samples) at the three NBS pooling centres (Leeds, Birmingham or Brentwood) using Tecan Genesis sample handlers. The 'minipools' are sent for automated testing to the National NBS NAT facility at the BioProducts Laboratory (BPL), Elstree. Their Qiagen robots are used for the extraction stage and amplification and testing is performed using Cobas/Roche Amplicor equipment. This strategy has enabled the NBS to accumulate stocks of NAT negative fresh frozen components.

In August, the NBS commenced a national recall, from hospitals, of all fresh frozen components still in stock and bled before 1st July 1999. These will be replaced with HCV RNA NAT negative stock so that transfusion of fresh frozen components on and after 1st September 1999 will be only from stock tested and found negative. The nature of this type of recall is such that it has not been possible to predict with great accuracy the amount of stock affected by the recall. If there are unexpectedly high hospital stocks of frozen components bled before 1st July 1999, it may take some time for the NBS to replenish these. The NBS is monitoring this situation closely and will ensure that individual patient management is not affected.

As NAT is currently performed in only one laboratory it was necessary to build collaborative contingency arrangements with the Scottish National Blood Transfusion Service into the planning process, in order to ensure continuity in the event of laboratory failure. These have now been fully tested and have proven reliable.

PHASE 2

The first stage of this process is to commission NAT laboratories at the three pooling centre sites, the aim being to transfer the amplification and testing technology consistent with that in place at BPL. Work is already underway at Brentwood with the intention to start testing there in November 1999. It is hoped to bring the Leeds and Birmingham laboratories on line by February 2000 and May 2000 respectively.

The additional laboratories will improve the robustness of this relatively new development in blood donor screening and are essential for the development of systems to allow the release of labile components. The latter requires much shorter timelines for testing than for frozen components and may involve the use of smaller 'minipools' and thus a larger number of tests.

For the time being NAT will continue to be used only for the release of fresh frozen components whilst the NAT Scientific and NAT Logistics Groups evaluate the implications, consider the results of scientific studies, draw up proposals for implementation and make recommendations to the NAT Steering Group. No firm date has been set for the introduction of HCV NAT for the release of labile blood components.

**NBS NAT Steering Group
September 1999**

BPL's Communication Strategy Wins Recognition

What an eventful time the last 18 months have been! During this period BPL has made the transition from fractionating only UK plasma to fractionating only plasma collected from specific centres in the USA. This simple statement hides a tremendous amount of antagonism, anxiety, soul-searching, resolution and recognition.

In February 1998, it became clear that fractionation of UK plasma was short-lived. The initial antagonism we felt towards the European regulators (CPMP), at that time, was only replaced by acute anxiety about the future, and particularly, about how we could best serve our customers and patients in England and Wales. After much soul-searching, and plasma-seeking, we decided that only the USA offered BPL the solution in view of both the quantity of plasma and the very high standards of operation of collection centres which we required. Selection of plasma collection centres and the amount of plasma to be purchased presented other challenges, which were satisfactorily overcome. While the donor review and acceptance procedures are more stringent than in the UK, BPL had to overcome the adverse perception of USA plasma. The weapon used for this aspect was to initiate NAT on 'minipools', comprising 512 donations, for HIV, HBV and HCV from the beginning. Of

course, we had to ensure that if any donation was found to be compromised, it could be removed before fractionation.

Another major logistical challenge was how to ensure that we could meet the needs of England and Wales for all our plasma products, while closing down production, cleaning and decontaminating the equipment and completing validation. From the start of fractionation to having the batch available for distribution takes two or three months. So, there would be at least four months during which no new batches of products would be available; inventory was needed to last throughout this period. BPL resolved to meet these challenges. However, there was another uncertainty. The plasma from the USA was obtained by apheresis in contrast to the recovered UK plasma, upon which almost all our manufacturing experience has been based. How would the new plasma behave in our processes? To identify any issues, the first three batches processed were not designated for clinical use, but for detailed evaluation by R&D and QC staff.

Even before the decision to switch the plasma source was made by the Department of Health, there was potential for speculation and rumour, which could confuse staff and customers. Therefore, BPL resolved to keep interested parties informed about the change-over, time frames and the ongoing status of the transition. Various meetings were held around the country as well as in association with relevant international meetings. Written documents were also produced to reinforce the oral presentations at these meetings.

In late June 1999, this communication programme achieved recognition within the UK pharmaceutical industry. BPL were winners of the coveted 'Professional Campaign of the Year' award, one of the Communiqué Awards for healthcare professional relations and medical education. Over 700 people from the pharmaceutical industry and allied healthcare groups were present to hear the announcement of the winners in a number of different categories. The panel comprised 24 independent professionals in Public Relations from pharmaceutical companies and agencies. The fact that BPL has limited resources, compared with most other pharmaceutical companies, made the win that more impressive, for example, Zeneca Pharmaceuticals and Solvay Healthcare and more than 30 other companies were short listed in the category won by BPL.

All available products are now derived from USA plasma. The first to be released were the intravenous immunoglobulins, Vigam-S and Vigam Liquid in mid December 1998, followed by Replene-VF, Replenate, 8Y and Zenalb in January 1999. An exchange system for UK plasma-sourced products is nearing completion. Normal intramuscular immunoglobulin is the last product to be made, because the usual plasma from the USA centres does not contain enough antibody to hepatitis A virus to meet the specification. Suitable hyperimmune plasma is now being collected to make the first clinical batch.

BPL would like to thank all customers for their help, support and understanding during this annus (et demi) horribilis!

**Dr Clive Dash, Medical Director, BPL
September 1999**