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25 March 1988

A PROFILE OF THE MANAGEMENT OF HAEMOPHILIA IN NORTHERN IRELAND

BACKGROUND

Fifty years ago the life expectancy of a severe haemophiliac was difficult to ascertain. In an historical paper in 1937 Carroll Birch investigated the final outcome of 113 such patients, only six survived to attain the age of 40 years. New treatment in the late 1960s and the innovation of a Home Care Programme in the early 1970s increased the life expectancy to 71 years in 1977. In 1988 once again, the expectancy of life becomes difficult to ascertain due to the passive infection of haemophiliacs by the Human Immunodeficiency Virus.

In Northern Ireland, the care of haemophiliac patients became formalised in the years 1958/59. Professor M.G. Nelson established the Haemophilia Centre in the Royal Victoria Hospital with support from the Medical Research Council (a grant was obtained to investigate and document patients). The Centre was located within the then designated Clinical Pathology Department.

TABLE

	1958	*1988*
Haemophilia A	*44*	*125*
Haemophilia B	*1*	*13*
Von Willebrand's Disease		*55*
Miscellaneous		*20*
(other inherited disorders)		

In the 1950s no true haemostatic treatment was available. Bleeding episodes were managed with infusions of fresh frozen plasma. It contained minimal amounts of the essential clotting proteins and could achieve only 10% of the required level. Joint bleeding and surgical intervention require levels of at least 60-100% of either factor VIII or factor IX respectively.

TREATMENT

In 1967 a milestone occurred; a revolutionary concentrate was produced called "cryoprecipitate". It was prepared from single plasma donation according to the methodology discovered by Poole, 1965. It was prepared initially in the Haematology Laboratory, Royal Victoria Hospital. Then the process was scaled up and taken over by the Blood Transfusion Service. No donor screening programme existed for the detection of viral hepatitis and many recipients developed clinical or subclinical hepatitis B. Nonetheless, the patients were ecstatic about the new treatment. A simple dental extraction was normalised and no longer constituted a major ordeal necessitating many weeks in hospital.

During 1971 cryoprecipitate was replaced gradually by commercially produced freeze dried/lyophilised factor VIII. It had a higher purity and a predictable potency. It became the routine treatment for severely affected patients, cryoprecipitate being reserved for mildly affected patients and those suffering from von Willebrand's disease. Thereafter, from 1974, the patients were encouraged to learn to treat themselves. This was to reduce or eliminate the endless hospital admissions, for example, a 28-year-old severely affected haemophiliac could expect as many as 200 admissions to hospital within that short span of years. Furthermore, it was postulated that early treatment would prevent the development of crippling joint bleeds. Within 10 years from commencement, all patients with adequate vein access and who had passed successfully the 3-month teaching programme, were placed on home treatment. The benefits accrued from this were as follows: hospital admissions became a rarity, only required for multiple complicated dental extractions, emergency or planned surgery: for example, a haemophiliac family with coexisting hyperparathyroidism had two members requiring surgery. One has already been completed and the second operation is planned for 1988/89.

Other benefits: uncomplicated dental extractions are now carried out as day patients. Furthermore, in career terms and employment, patients have been able to attend school regularly, maintain courses at polytechnics and achieve degrees at university. One such patient qualified in medicine and is now in practice in England: another patient who used crutches and never played any games at commencement of treatment is now at university, has a single figure golf handicap and has played cricket for the Ulster Schoolboys. He has required no hospital admission for over 10 years.

COMPLICATED TREATMENT

However, a core of complicated patients remains. They constitute the group who develop an anti-factor or an inhibitor in the blood which renders infused human factor VIII ineffective. Six to 10% of this type of haemophiliac exists worldwide. The present incidence in the U.K. is 5.95%. In Northern Ireland, in the past it has reached 16%. However, in recent years, two such patients emigrated to Canada, one moved to Glasgow and three others have died. There are now 11 patients requiring the most expensive and complex management in the Province. One such patient used 880,000 units of FEIBA last year (1987) to cover many life-threatening bleeding episodes and six essential surgical operations required following a severe accident. FEIBA costs 30 pence per unit. This patient died on 20 March 1988. Ten further patients remain. In this category only severe joint bleeds, life-threatening injuries and essential surgery operations are treated. However, it may be noteworthy that only one of the 10 remaining patients is HIV positive.

H.I.V. POSITIVITY

The HIV antibody positive rate for severely affected patients in the U.K. is 54%, with some centres having ratings of 75-80%. In Northern Ireland only 16 patients have been shown to be antibody positive. This is equivalent to 25% of the most severely affected patients and 16.5% of all treated patients in the Province. The figures may be explained on the basis of the transfusion policy operated in the Haemophilia Centre since home treatment began in 1974. A single commercial product was used for all home treatment patients and a second product was used for the rest. Thus, patients

were exposed to a regular and restricted number of donors. It is probable that exposure to many different commercial products resulted in the higher positivity ratios in other centres. Despite using the same quantity of factor VIII per patient per year, the Northern Ireland positivity percentage is equivalent to that in Edinburgh, which only used local material from the Blood Transfusion Service and at no time used commercial concentrates from whatever source. In addition, all the severely affected patients in Northern Ireland were placed on product A for both home treatment and inpatients. It so happened that this product was of European origin which became contaminated at a later date compared with American products. It is likely that this caused the smaller number of positivities in the Province - a saving, hopefully, in the future as there will be fewer patients to develop the fullblown acquired immunodeficiency syndrome.

FUNDING OF TREATMENT

The funding of therapeutic materials for the Haemophilia Centre has not been clearly thought out and appropriate guidelines established. Perhaps this is understandable from the sequence of events and historical background which has been presented. From 1971 onwards, the cost of purchasing commercial blood products for complicated and uncomplicated patients was borne by the Royal Victoria Hospital Pharmacy budget. In the early 1980s, when it seemed ridiculous that one small hospital budget should sustain the haemophiliac population of the Province, the purchasing power was transferred to the Blood Transfusion Service. In or about this time, commercial factor VIII was decreased and the purchasing of NHS factor VIII from the Scottish Home and Health Department was commenced. Although this is

less expensive than commercial material, it still costs approximately eightpence per unit. Plasma is donated and efficiently transported by the Blood Transfusion Service. A charge is made for fractionation and appropriate heat treatment and material is returned to the Province. For a small number of patients who are undergoing planned surgery, it has been the practice during the past two years to buy the best pasturised commercial factor VIII product, namely Profilate. It is and has been used to provide haemostatic cover for planned surgery, for example, the parathyroidectomy as referred to earlier. Patients who weigh more than 80 kgs. require such a volume of the NHS material, due to low number of units per 20 ml bottle, that it becomes impractical to try and infuse appropriate quantities prior to surgery without producing circulatory overload. Furthermore, it has been agreed that heat treatment sometimes renders the haemostatic effect of the material less effective. Therefore it is necessary to maintain a store of this commercial material. Despite the purchase being carried out by the Blood Transfusion Service on behalf of the Centre, all material utilised is retained within the computer base in the Royal Victoria Hospital Blood Bank. This ensures that the Director of the Haemophilia Centre monitors all usage of blood products throughout the Province. The patients are totally regional in origin and in England the funding is provided by the regional health authority. In Scotland treatment is funded by the Scottish Home and Health Department. It would seem appropriate that the cost of treating haemophilia in Northern Ireland should be borne by the Department of Health, or on a basis of cross-accounting for each Board. The Eastern Health Board should not have to bear the full brunt of this expensive treatment.

The United Kingdom Haemophilia Centre Directors collect data from all treatment centres and statistics are prepared annually. Appendix A shows the annual increment of usage of factor VIII material and other statistics. The consensus of opinion is that it will continue to increase, due to further surgical orthopaedic procedures being necessary to aid patients motility and mobility in the hope of decreasing hospital admissions and gaining employment. Two to three such orthopaedic operations are carried out in the Province annually, for example, over the past five years:

(1) hip replacement,

(1) knee joint replacement,

(3) synovectomy,

(3) arthroscopy

(3) manipulation to relieve fixed flexion deformity, etc.

Professor R.A.B. Mollan, Professor of Orthopaedic Surgery, and Dr. E. Mayne, Director of the Haemophilia Centre, hold a joint haemophiliac/orthopaedic clinic every three months. In 1986 in the U.K. the usage of factor VIII per haemophiliac per year was 37,966: the amount per patient per year in Northern Ireland for 1986 was 32,582 units. In 1987 the figures have just been calculated for Northern Ireland and indicate a reduction to 26,985 per patient per year. The average amount for treatment per year in the United States of America is 80,000 units and in Sweden, for regular users, 100,000. If prophylaxis, i.e. preventative factor VIII is used on a regular twice-weekly basis, 200,000 units are used per annum. These figures apply to uncomplicated haemophilia.

During the next few years, it is not practical or possible to give an accurate budget requirement. However, during the last month, one of the major users in the complicated patient group died. He was the individual who required 880,000 units of FEIBA last year. Barring accidents, this should decrease the budget for complicated haemophiliac patients by approximately £250,000 per annum. This leaves 10 patients in this category to be funded.

In 1986 in the U.K. (see table 7) 1.553 million units of FEIBA were used. This doubled the 1985 usage at 814,000 units. The 1987 figures are not yet available but all agreed that a further doubling of the figure is likely, the reason being that in 1986 an alternative treatment was available, namely NHS factor IX concentrate, of which 1.459 million units were used. This material has become ineffective due to heat treatment, hence the doubling of requests for the more expensive FEIBA. In 1987 the Northern Ireland Centre used 1.916 million units of FEIBA. On the basis of an expected reduction of almost 900,000 units, a projected budgeting for 1988/89 would be 1.2 million units of FEIBA to cover unexpected eventualities and the usual treatment courses. plus the NHS factor for routine usage.

Dr. Mayne would be happy to meet with appropriate members of the Board or Department to discuss these funding arrangements.

GRO-C

B. E. Mayne
Director
N.I. Haemophilia Reference Centre

APPENDIX A

ANNUAL RETURNS FOR 1986

The attached tables and graphs contain the information available from the UK Haemophilia Centre Directors' Annual Returns. Returns have been received from 102 Centres.

Number of patients

By 31.12.86 there were 5,087 haemophilia A patients known to Haemophilia Centres (Table 1). This is an increase of 75 compared with the previous year. Forty per cent of these patients were severely affected with factor VIII levels <2% average normal. The incidence of antibodies to factor VIII is still approximately 6% of all haemophilic patients (Table 2). The number of new factor VIII antibody cases is shown in Fig. 1.

The total number of patients with Christmas disease now stands at 949 which is 30 more than in the previous year. Thirty three per cent of the patients are severely affected. Antibodies to factor IX were reported in 7 cases (Table 3). This is unchanged from the previous year.

The number of patients reported as suffering from von Willebrand's disease has risen to 2,040 which is 163 more than in 1985. Forty five have factor VIII:c levels <2% of average normal and of these 24 required treatment in 1986 and 9 were on home therapy. Forty per cent of all von Willebrands patients treated had factor VIII:c levels greater than 30% of normal. Three patients with von Willebrands disease had antibodies to factor VIII (Table 2).

Treatment of patients

Of the 5,087 haemophiliacs registered 2,343 (46%) received replacement therapy in 1986 (Table 1) and 1,285 were receiving home therapy. The total amount of factor VIII used at Haemophilia Centres in 1986 was 88.5M an increase of 11M compared with the previous year (Table 5 and Fig. 2). Most of this increase was due to increased usage by haemophiliacs. Patients with von Willebrands disease used 1.96M compared with 1.78M in 1985 (Tables 5 and 11). The amount of NHS factor VIII used rose by 8.4M and the amount of commercial factor VIII fell by 2.8M compared with 1985. The average amount of factor VIII used by haemophiliacs per patient per year has increased by approximately 4,000 units to 37,966 units when compared with 1985.

A total of 6M units of human factor VIII was used to treat 155 haemophilia A patients who had factor VIII antibodies (Table 7). In addition 1M units of porcine factor VIII, 1.5M units NHS factor IX, 1.5M units FEIBA were used.

Table 7

Materials used by Haemophilia Centres in 1986 to treat 155 Haemophilia A patients who had F.VIII antibodies. In addition, 10 other patients were treated but received no doses

Material	Factor VIII units Used at Hosp.	Supplied for HT	Total F.VIII units
Plasma	-	-	-
Cryoprecipitate	62,000	3,000	65,000
NHS F.VIII conc.	747,000	772,000	1,519,000
Commercial Human F.VIII conc.	2,627,000	1,842,000	4,469,000
Total Human F.VIII conc.	3,436,000	2,617,000	6,053,000
Porcine F.VIII	854,000	224,000	1,078,000
Other Materials:	Units	Units	Units
FEIBA	1,002,000	551,000	1,553,000
AUTOPLEX	587,000	5,000	592,000
NHS F.IX conc.	763,000	696,000	1,459,000
Commercial F.IX conc.	244,000	203,000	447,000

Table 6

Materials used for treatment of Haemophilia A patients during 1986 and the amount used for Home Treatment

Material	Total F. VIII units used for all Haemophilia A patients	F.VIII units used for Home Treatment only	% used for Home Treatment
Plasma	7,000	Nil	-
Cryoprecipitate	1,620,000	248,000	15.31
NHS F.VIII concentrate	31,221,000	20,024,000	64.14
Commercial F.VIII conc.	53,448,000	31,272,000	58.51
Total units	86,296,000	51,544,000	59.73
Number of patients treated	2,273	1,285	56.53
Average amount used per patient	37,966	40,112	-

50 inc ptsoi Kmethrapy.

In addition, NHS F.IX, Porcine F.VIII, FEIBA and AUTOPLEX were supplied for HT to Haemophilia A patients with F.VIII antibodies (see Table 7)

Copies to:

Miss J. Kells, Planning Department, EH&SSB

Dr. P.M. Darragh, Community Physician, EH&SSB

Dr. A.E. Greer, Acting CAMO, EH&SSB

Dr. J.D. Laird, Chairman, Medical Executive, RVH

Dr. W.M. McClelland, Director, NIBTS

Dr. S.I. Dempsey, Consultant Haematologist, RBHSC

SUPPLIES OF BLOOD PRODUCTS

1 INTRODUCTION

The purpose of this paper is to draw to the attention of clinicians the emerging problems with respect to the supply of blood products and in particular plasma products.

All plasma products used by hospitals in Northern Ireland are supplied from the NI Blood Transfusion Service usually via hospital blood banks. These plasma products which include Factor VIII, Albumin and Immunoglobulins are manufactured by the Protein Fractionation Centre, Edinburgh using as raw material, plasma supplied by NIBTS.

A wide variety of plasma products are available, many of which have specialised applications. This paper deals with 3 products, fresh frozen plasma, plasma protein solution and 20% albumin, all of which are used in many clinical specialties.

During the past few years the usage of these three products has increased dramatically in Northern Ireland. The financial costs have been substantial and the capacity of the Blood Transfusion Service to respond to the increased demand stretched to the limit. Furthermore, as the increasing demand shows no sign of slackening it is opportune to review current usage patterns. This has become particularly important because as described below further increases in plasma supply will require an entirely new production strategy which in turn would have major cost implications.

2 Pattern of Usage

The tables in Appendix I demonstrate the increasing usage by hospitals of plasma protein solution, albumin and fresh frozen plasma. It is important to note that as usage of fresh frozen plasma increases a corresponding reduction in plasma is available as raw material for the manufacture of blood products.

A detailed analysis of figures from England, Wales and Scotland has revealed that usage rates per million population of 20% albumin and fresh frozen plasma are substantially higher in N Ireland - in the case of 20% albumin as much as 5 fold higher!

The approximate costs of blood components, plasma fractions and some alternative fluids used for volume recuscitation are tabulated in Appendix 2.

3 The Problem of Plasma Supply

Until recently the amount of blood collected from donors was largely dictated by the requirement for red cells (whole blood, red cell concentrates etc). Plasma was harvested from these units as a 'by- product ' and used either for direct transfusion to patients (as fresh frozen plasma) or for the manufacture of purified protein derivatives. Over 90% of blood donations are now processed and by using optimal additive solutions (SAG-M)for cell suspension the maximum possible amount of plasma is now been harvested from the available supply of blood.

Demand for red cell transfusions has remained fairly static and any further increases in plasma collection can only be achieved by either:

a. Additional blood donations which are used for plasma only (the remainder of the blood being discarded.

b. Plasmapheresis programme - a technique by which plasma is collected directly from donors.

Both of these options are expensive compared to the current method of plasma procurement.

The further option of purchasing plasma products from commercial sources is likely to be even more expensive and in any case conflicts with present Government policy of self-sufficiency in blood products.

4 Reasons for increased usage of Plasma Products

A number of possible factors have led to this increase.

a. Clinical efficacy and new therapeutic applications. It is important to stress that the changing patterns described above do reflect a trend towards blood component therapy which is being encouraged by all experts in the field. This general approach undoubtedly makes the best use of available blood supplies and is considered to be in the best interests of patients as a whole.

b. Decreased availability of whole blood. This may account for some of the increased usage of albumin and fresh frozen plasma but if so it is debatable if this can be justified.

c. Ready availability of plasma products and unawareness of any limitations in supplies.

d. No financial constraints on clinical users. As all plasma products are supplied from the Blood Transfusion Service which receives separate funding from the Eastern Area Board the costs have no direct impact on hospital budgets. If the latter did apply it is possible that users would choose less expensive products for transfusion eg crystalloids or synthetic plasma expanders instead of plasma protein or albumin.

5 Recommendations

In view of the above it is important that mechanisms are established which ensure that clinical users of blood products are made aware of the current constraints and costs involved in their supply.

The following approaches are recommended:

Hospital Transfusion Committee

Each acute hospital should establish a Blood Transfusion Committee composed of representatives from the major clinical specialties as well as the hospital blood bank. A representative from the Blood Transfusion Service (ex officio) should also be included. Apart from providing a mechanism for auditing usage of blood and blood products such a Committee would of course, address all aspects of transfusion medicine within the hospital.

Guidelines for use of blood and blood products

While it is expected that the production of agreed guidelines for the use of blood and blood products would be an important function of hospital transfusion committees there could also be considerable benefit if guidelines for use throughout the province could be agreed. These might cover specialised clinical areas eg use of blood products in intensive care units, and be drawn up and agreed by groups of appropriate specialists.

A number of relevant guidelines produced by National Committees (UK and USA) have been published recently as follows:

Guidelines for transfusion for massive blood loss. A publication of the British Society for Haematology. Clinical and Laboratory Haematology, 10:265-73, 1988.

Consensus conference. Fresh frozen plasma. Indications and risks. JAMA 1985:253,551-3.

Consensus conference. Platelet transfusion therapy. JAMA 1987:257,1777-80.

Handbook of Transfusion Medicine. UK Blood Transfusion Services. Published by HMSO. In press.

Request Forms

A specific recommendation is that formal procedures involving the use of request forms should be used when ordering all blood products, including plasma protein solution and albumin. Apart from facilitating monitoring and control this approach is highly desirable as a means of maintaining proper records and ensuring that all blood products are fully accounted for.

ANNUAL USAGE OF ALBUMIN (PLASMA PROTEIN SOLUTION + 20% ALBUMIN) - N IRELAND

YEAR	PLASMA PROTEIN SOLUTION 20g/BOTTLE	20% ALBUMIN 20g/BOTTLE
1980	5006 bottles	2259 bottles
1981	5220 bottles	2361 bottles
1982	7275 bottles	2184 bottles
1983	9012 bottles	2310 bottles
1984	9806 bottles	2752 bottles
1985	11432 bottles	2940 bottles
1986	11804 bottles	2950 bottles
1987	13681 bottles	5077 bottles

ANNUAL ISSUES OF FRESH FROZEN PLASMA FROM NIBTS

YEAR	FRESH FROZEN PLASMA 220 ml/unit
1980	1574 units
1981	2396 units
1982	4943 units
1983	4883 units
1984	6795 units
1985	7945 units
1986	8355 units
1987	9217 units

APPENDIX 2

1988/89 Prices of Blood Components and Plasma Fractions

Blood Components (Based on DHSS Handling Charges to Private Sector)

Whole Blood	£26
Concentrated Red Cells	14
Platelet Concentrate (1 donation)	14
Fresh Frozen Plasma (200-250 ml)	12

Plasma Fractions (Based on Commercial Suppliers Charges)

Plasma Protein Fraction (5% Albumin)	400 ml	£35
20% Albumin	100 ml	35

Prices of Other Fluids for Volume Resuscitation

Crystalloids

Sodium Chloride	500 ml	£0.5
Ringer's Lactate	500 ml	0.5

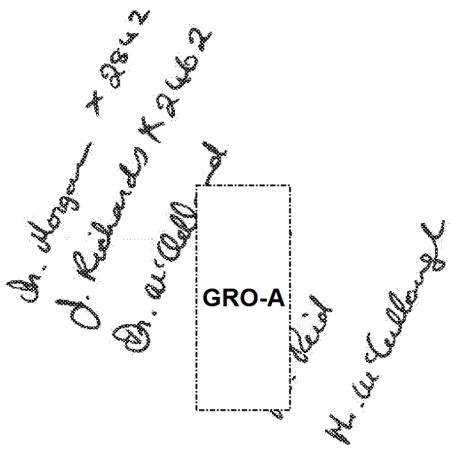
Non Plasma Colloids

Dextran 40	500 ml	£2.5-6.5
Dextran 70	500 ml	4.0-5.0
Haemaccel	500 ml	3.8
Hetastarch	500 ml	15-16
Gelofusin	500 ml	2.5-3.0

Note for file

Meeting with representatives of B.C.H. and B.T.S. to discuss the recharging of costs of blood products to other Boards was held on 4th May 1988. Action was agreed and the B.C.H. UoM will be writing to us on the various issues.

E.J.A. McCullough
9.5.88



GRO-C: CA

File No. 847/86

Committee: Area Executive Team

Meeting held on: 13 April 1988

Subject: Blood Transfusion Service

LA
CSA

DECISION

78/88 BLOOD TRANSFUSION SERVICE

AGREED that an urgent meeting should be set up with the Permanent Secretary (GM, CAMO, Treasurer and CAPO to be present - GM to make arrangements) to discuss the funding of the above service and, in particular, to emphasise that the Board cannot continue to carry the associated liability (even retrospectively). GM

FURTHER AGREED to communicate (through the Treasurers) the Board's insistence on recoupment for items purchased on behalf of the other Boards. It will therefore be necessary to ensure that there are adequate mechanisms for charging and AGREED that Treasurer, CAMO and CA should nominate officers to monitor the cost, quantity and activities of the service. Treasurer CAMO CA

GRO-C

Separate A/s to GM

Treasurer

CAMO

U/Fl/1

B/F 4/5/88 at 11.00am

with Rev Sec. I.T. -
G.M., Treas., D'Gen, D'Pers.

NORTHERN IRELAND BLOOD TRANSFUSION SERVICE

= COPY FROM I&F.

A summary of the main reasons for the increased expenditure in the Blood Transfusion Service is provided below, with details shown in Appendices.

Background

In simplified terms, the function of the Northern Ireland Blood Transfusion Service is to receive donated blood which is then separated into plasma, red cells and platelet concentrates; a large proportion of the plasma being sent to a Fractionation Centre to produce a range of blood products. It is also necessary to obtain supplies commercially to supplement fractionation supplies. In recent years it is the availability of other clotting agents as alternatives to the Factor VIII provided by the fractionation process, which has been the major cause in the escalation of Blood Transfusion Service total expenditure.

Blood Products

1. From the Protein Fractionation Centre, Edinburgh.

Prior to 1982, most blood products provided through the Blood Transfusion Service were acquired from the Blood Products Laboratory at Elstree free of charge, but since 1982 when the service was transferred to the PFCE, the Blood Transfusion Service has been required to pay for all products supplied and in turn has sought to recharge other Boards for products provided to hospitals outside the Eastern Board.

Growth in the cost of this service is shown at Appendix 1.

2. Commercial blood products required in place of or as a supplement to PFCE supplies.

Agreement is reached each year between PFCE and the respective user Blood Transfusion Services as to the volume of plasma to be supplied and as to the volume and type of blood products to be produced. The Northern Ireland Blood Transfusion Service receives three main groups of blood products:

(i) Albumin
(ii) Immunoglobulin (mainly intravenous)
(iii) Clotting Agents (mainly Factor VIII)

These commercially produced blood products which were acquired either in preference to PFCE products or as a top up for limited PFCE supplies, were purchased centrally for the Northern Ireland Region by the Blood Transfusion Service with effect from 1 January 1985, and these too are charged to other Boards on an actual cost basis.

The indebtedness between the Eastern Board and other Boards in respect of (1) and (2) above is shown in Appendix 3.

3. Supplies to the Haemophilia Centre, RVH

All clotting agents (Factor VIII, Factor IX, etc) are managed exclusively in the Haemophilia Centre, Royal Victoria Hospital, under Dr. Mayne, the Centre Director. All supplies of clotting agents whether obtained from PFCE and routed through the Northern Ireland Blood Transfusion Service, or obtained directly from commercial sources, eg Profilate, Hyate, Feiba, Autoplex, must be delivered directly to the Haemophilia Centre.

Mr J Carville, the Senior Chief MLSO in the Blood Bank, RVH, under the direction of Dr Mayne, is responsible for the ordering and control of all clotting agent supplies.

As the Haemophilia Centre is solely responsible for the provision and management of all clotting agents, all supplies required either for EHSSB patients or for patients admitted to hospitals outside the Eastern Board are issued in respect only of named patients under Mr Carville's control.

Growth in the cost of supplies of clotting agents to the Haemophilia Centre are shown in Appendix 1, mainly under Clotting Agents, and to a much lesser extent within PFCE supplies.

Appendix 2 sets out the projected overspending for 1987/88.

The Northern Ireland Blood Transfusion Service bears the cost of all clotting agents issued from the Haemophilia Centre in respect of supplies provided for patients in hospitals outside the Eastern Board and for home use at non EHSSB addresses. It has not been the practice to seek recovery from other Boards to date.

The major cause of increased costs has been the availability of improved treatment for the rare group of inhibited haemophiliacs (11 people in Northern Ireland at present) who do not receive relief from the 'normal' Factor VIII produced by PFCE. The cost for these treatments was approximately £1.2m in 1987/88.

The options open to the EHSSB would be:

(1) Stop providing PFCE supplies for those Boards which refuse to pay. This would have implications for the process from blood donation through to PFCE deliveries of blood products.

(2) Stop providing commercial blood products which are required in place of or to supplement PFCE supplies to those Boards which refuse to pay. This would be a reasonable decision, merely reverting to the position prior to 1 January 1985 when all Boards handled their own needs for commercial supplies.

(3) Clotting Agents bought commercially could really be viewed as specialised drug supplies rather than as part of the "Regional" Blood Transfusion Service function so there would be a strong argument either to charge other Boards fully OR for Northern Ireland Blood Transfusion Service to be fully and properly funded as a Regional Service.

Funding provided by the Department for Blood Transfusion Services amounted to £0.440m in 1984/85 (as part of £1.0m non-capital development); and £1m in 1987/88 as part of Regional Medical Service allocation. The overspending position of £0.940m in 1987/88 takes these allocations into account.

Appendix

N.I.B.T.S.

Summary of Expenditure 1983/84 to 1987/88 (Estimated)

	1983/84	1984/85	1985/86	1986/87	1987/88
Staff Costs	913,047	997,090	1,089,337	1,178,635	1,281,880
GOODS AND SERVICES					
Laboratory Supplies	284,838	381,828	425,639	440,741	(Estimated) 266,000
Blood Products					
PFCE	)	529,665*	368,393	431,229	455,000
PFCE Supplementary	907)	134,553	132,026	262,106	332,000
Clotting Agents	)	8,051	247,873	703,179	1,218,000
Bone Marrow CMV	)	-	31,391	19,875	64,000
Transport, Travel, etc	114,801	119,019	135,949	156,370	162,000
Sundry Other (Inc VAT)	223,855	244,449	314,811	334,917	313,000
	624,401	1,417,565	1,656,082	2,348,417	2,810,000
TOTAL	1,537,448	2,414,655	2,745,419	3,527,052	4,091,880

NB: * The first account paid to PFCE in 1984.85 was in respect of:

1982/83	164,865
1983/84	189,800
Estimate for 1984/85	175,000
	529,665

The actual cost for 1984/85 (not available for 12 to 15 months) was £306,500. All current PFCE costs are estimated.

0532N

Projected Financial position for year ended 31 March 1988

		£	%
Salaries and Wages	Overspent	40,000	4.0
Goods and Services	Overspent	900,000	45.0
		940,000	32.0

The overspendings reflect laboratory staff under Salaries and Wages, and within Goods and Services almost entirely the purchase of blood products from commercial sources charged to the laboratory budget.

Estimated total expenditure on Goods and Services for 1987/88 can be summarised as follows:

		£	%
Laboratory		2,335,000	83
Staff Travelling & Subsistence	100,000		
Transport maintenance & Hire	62,000	162,000	6
Other		193,000	7
VAT (Not payable on Blood Products)		120,000	4
		2,810,000	100

Laboratory expenditure for 1987/88 can be further analysed:

	£
Glassware, chemicals	156,000
Nitrogen gas, blood taking and processing equipment, etc.	71,000
Chemicals associated with the AIDS programme	39,000
	266,000

Protein Fractionation Centre, Edinburgh			
Blood Products		455,000	
Other Commercial Blood Products in place of or to supplement PFCE supplies		332,000	
		787,000	
Commercial Blood Products			
Profilate)	181,000		
Hyate)	155,000		
Feiba)	842,000		
Autoplex)	40,000	1,218,000	
Cytotect CMV (Bone Marrow)		64,000	
			2,069,000
			2,335,000
Laboratory Budget 1987/88			1,445,000
		Overspending	890,000
Sundry Other overspendings 1987/88			10,000
			900,000

0530N

Indebitedness between Eastern Board and other Boards in respect of PFCE supplies and supplementary supplies obtained from commercial sources

	FRACTIONATION	COMMERCIAL	TOTAL
Southern Board 1.4.86-31.3.87	43,128	29,489	72,617
1.4.87-31.3.88	34,777	22,972	57,749
	77,905	52,461	130,366
Western Board 1.4.85-31.3.87	32,048	4,260	36,308
1.4.87-31.3.88	32,429	22,946	55,375
	64,477	27,206	91,683
Northern Board 1.4.87-31.3.88	27,056	13,290	40,346
Owing as at 31 March 1988	169,438	92,957	262,395
As at 31 March 1987	75,176	33,749	108,925
1987/1988	94,262	59,208	153,470
	169,438	92,957	262,395

N.B. 1. Northern Board has accepted the principle of charging and has cleared all charges raised up to 31 March 1987. Charges shown about for 1987/88 are book balances as at 31 March 1988 which it is expected will be paid in due course.

2. Western Board has accepted the principle of charging for commercial blood products only and has cleared all but a small disputed balance raised up to 31 March 1987. The charges for 1987/88, £22,946 are expected to be paid in due course but the £64,497 for all PFCE supplies to 31 March 1988 remains in dispute.

3. Southern Board does not accept the principle of charging at all.

0530N

EASTERN HEALTH & SOCIAL SERVICES BOARD

THE N. IRELAND BLOOD TRANSFUSION SERVICE

1. This paper describes the function of the Blood Transfusion Service, current trends and possible future developments.

2. The N. Ireland Blood Transfusion Service is a Regional Service administered by this Board. It is responsible for:-

   (a) The collection of blood from donors, the testing and processing of blood into various components and their distribution to hospitals throughout N. Ireland.

   (b) Testing blood from all pregnant women in the Province. These tests are important in preventing certain diseases affecting the baby eg. Rhesus disease, syphilis and congenital abnormalities due to rubella.

   (c) Providing a blood group reference service.

3. The N. Ireland Blood Transfusion Service currently has 140,500 persons on its donor panel. This has grown by 46% since 1980. Hospital activity has also grown over this period with admissions and operations having increased by 11% and 20% respectively. Sixty-six thousand persons donated blood during the past year and 53,000 Units of blood were issued.

   Up to 10 years ago most blood collected from donors was issued to hospitals and transfused as whole blood. Now 80-90% of blood collected is processed into separate components. Some of these components are produced at the Transfusion Centre and others in Scotland by the Scottish Blood Transfusion Service using plasma supplied by the N. Ireland Blood Transfusion Service.

4. Blood is the transport medium of the body. It can be divided into two main parts:-

   (a) Cellular component

   (b) Fluid component (plasma).

The cellular components include red cells which transport oxygen around the body, white cells which are essential in combating infection and platelets which are involved in clot formation.

Plasma is a very complex fluid. It contains chemicals such as sodium and calcium as well as protein, fats and hormones.

The following components can be prepared from one blood donation:-

(a) Plasma, which can be frozen soon after collection and used as such later or which can be chemically fractionated to produce:-

(i) Factor VIII (see below).
(ii) Albumen (see below).
(iii) Immunoglobulin Solution. This is administered to people at risk of contracting certain infectious diseases.

(b) Red cells.

(c) Platelet concentrate.

5. Current Trends

The amount of blood donated has only slightly increased over the past few years. However, there has been a marked increase in demand for various blood components.

(a) Factor VIII. This is used in the treatment of haemophilia. Demand has increased by 80% over the past 5 years. This increasing demand reflects increasing surgery on haemophiliacs, particularly orthopaedic surgery, more haemophiliacs are now using home treatment and there is an increased prevalence of haemophilia due to better detection techniques and treatment. In 1937, only 6% of haemophiliacs survived to age 40 in contrast to 1977 where the average life expectancy was only one year shorter than that of a non-haemophiliac ie. 70 years of age.

(b) Plasma. Demand has more than doubled since 1980. Part of this has been due to increased activity and change in clinical practice in cardiac surgery, treatment of burns and intensive care. It is also being used more frequently in the treatment of leukaemia and in the preparation of some patients for surgery.

(c) Albumen. Demand has increased by 30% since 1980 for many of the reasons outlined in (b).

(d) Plaletets. Demand has trebled since 1980. This has been mainly due to more intensive treatment of haematological disorders, the development of bone marrow transplantation and the growth in cardiac surgery.

6. The need for self efficiency

Whereas the demands for conventional blood transfusion have only slightly increased in recent years, there has been a marked increase in demand for blood products, particularly Factor VIII and albumen as described above. Some of this demand has, in the past, been met by the use of commercial blood products. It is preferable for the following reasons that extra demands should be accommodated through the N. Ireland Blood Transfusion Service.

(a) Cost. It is cheaper to produce blood products through the Blood Transfusion Service than buying commerical material. There is currently a world shortage in albumen and its cost has doubled during the past 12 months to £55/20g bottle. NHS produced albumen is less than a quarter of this price.

(b) Patient Safety. Blood is donated voluntarily within the UK. This is in contrast to other countries eg. USA where people are paid to donate blood. Some people may use this mechanism as a source of income. The source of commercial blood is paid donors and therefore the risk of transfusion transmitted diseases ie. AIDS and hepatitis is much greater than from voluntary donors, especially in areas of low risk of these infections (Scotland and N. Ireland).

All blood donated within the UK is screened for the AIDS virus and that causing hepatitis.

(c) Ethical Reasons. Intensive collection of blood plasma as practised by commerical companies in other countries may be detrimental to the health of donors who are often the most poorly nourished in the community. This may jeopardise blood collection in these countries where blood is already in short supply.

7. Developments

(a) The Board's Area Strategic Plan proposed that the number of operations in cardiac surgery should increase and orthopaedic surgery is also increasing. Cardiac and hip replacement surgery places heavy demands on the Blood Transfusion Service.

(b) Demand for Factor VIII and Albumin will continue to increase. This means that more plasma will require to be collected. This is not simply a matter of increasing blood collection at donor sessions as this would be a most expensive and at times wasteful procedure. By using new technology it is possible to provide an extra 3,000 litres of plasma per year. Factor VIII and albumin are then prepared from this plasma in Scotland.

(c) Platelet demand has increased 360% since 1980. This growth in demand is expected to continue with increased cardiac surgery, bone marrow transplants and leukaemia treatments.

(d) The development of bone marrow transplantation in N. Ireland will be shortly reviewed. An increased number of bone marrow transplants will generate additional demands for plasma, platelets and other blood products. Bone marrow transplantation also depends on finding a suitable donor. This means tissue typing a pool of potential donors. A national charity has offered to fund the cost of tissue typing donors but the Blood Transfusion Service would be required to recruit and administer the Bone Marrow Donor Panel.

(e) Autologous Transfusions. This is where patients donate their own blood during the few weeks prior to surgery for subsequent transfusion. Some hospitals in England are already offering this service. However, it should be noted that only a minority of patients receiving transfusion would be suitable for this technique.

The advantages are that it avoids transfusion transmitted infection and blood group incompatibility. The disadvantages are that it is only suitable in a minority of cases and that it could undermine public confidence about the safety of blood transfusion.

A pilot study on autologous transfusion is being conducted in Scotland. A similar study may need to be peformed in N. Ireland to estimate costs and operational difficulties.

(f) Screening for non-A, non-B hepatitis. Post transfusion hepatitis (non-A, non-B type) is one of the more serious late complications of blood transfusion. The incidence in the UK is thought to be 2-5% of transfusions. Some patients may as a result develop chronic liver disease and ultimately cirrhosis.

There is no specific laboratory test to detect a carrier for non-A, non-B hepatitis. However, several countries use indirect methods to screen for this condition. This practice may become mandatory throughout the UK from 1988 to comply with new EEC regulations. Scotland is proposing to adopt this method of screening and should this be adopted, NI will be obliged to follow suit, otherwise they may not accept plasma from NI for processing.

(g) Intravenous Immunoglobin. This became available in 1985. The usage rate is rapidly increasing. This new preparation is being used mainly by haematologists in the management of certain haematological conditions. Despite its recent introduction it is now being used routinely in the management of some of these conditions. As this preparation is evaluated other uses for it may emerge. So far little scientific evidence is available about its effectiveness.

(h) Increased accommodation. The Board's Regional Strategic Plan has acknowledged the increasing demands on the Blood Transfusion Service and agrees the need for urgent rehousing of the Blood Transfusion Service in purpose built accommodation, ideally on the site of a major teaching hospital. Such a location would allow the Blood Transfusion Centre to be more actively involved in patient care.

8. Cost

Blood Transfusion is a demand led service with increasing activity generating a demand for blood and blood products. Until April 1982, NHS blood products for N. Ireland were produced in England free of charge. Since that date plasma fractionation for N. Ireland is performed in Scotland and the Blood Transfusion Service is billed accordingly.

Prior to 1986 commerical supplies were purchased as required by individual hospitals. Since then such products are ordered through the Blood Transfusion Service and charged to the appropriate Health & Social Services Board. The cost of plasma and blood products for the year ending March 1987 was £1.42 million. The total expenditure for the N. Ireland Blood Transfusion Service in that year was £3.53 million.

As the cost of blood and blood products consumed by a hospital, whether commerically or NHS produced, is not met at Unit of Management level, there is a risk that they may not be used in an effective and economical matter. The RVH commenced an informal monitoring mechanism in December 1986 to address this issue. However, it should be noted that in 1985 40% of total albumen and 60% of immunoglobin were issued outside the EHSSB.

9. Conclusion

The Blood Transfusion Service is a most important regional service. It provides an important screening service and acts as a manufacturing base for various blood products. Demand for these products has increased because of increased clinical activitiy throughout the four Boards and also because of new clinical developments. There is a need to become self sufficient in these products. There are many developments within blood transfusion and these will require careful evaluation before they become standard local practice. However, it may be mandatory to adopt some practices used elsewhere in the UK. There is a need for each hospital in the Province to monitor its use of blood and blood products.

The Board has received preliminary estimates of the financial consequences of the developments outlined in 7(a) - (g) which amount to £442,000 revenue and £100,000 capital. There is a need for the Board to explore and confirm its policy in some of these issues and to clarify the areas in which funding for blood products may overlap with allocations for Regional Services. Reference has been made in the Operational Plan for 1988/89 to the need for investment in the Blood Transfusion Service.

Peter [illegible] (Fax) John — comp. haem
— also if you want
the amount spend £900K.

John McGrath needs figures for PES on Blood Products by Thus 31/3/88.

file BTS

I'm not clear on the politics given Paul Crick's figures & comments.
Would it be OK to ring & say :—

1. Complicated haemophilia
   - 11 patients at present
   - incidence in N.I. approx 6%
     in UK 6%
   - uses product Feiba
     2,806,000 units 1987/88
   - approx cost £842,000.

(2) Do I need to mention overall funding deficit of Blood Products? —
What is happening to these monies? To Janet 30/3

PPA

847/86

NORTHERN IRELAND BLOOD TRANSFUSION SERVICE

Projected Financial position for year ended 31 March 1988.

		£	
Salaries and Wages	Overspent	43,000	
Goods and Services	Overspent	900,000	943,000

The overspendings relate to laboratory staff in Salaries and Wages, and within Goods and Services, wholly to expenditure under the Laboratory heading which can be analysed as follows:

			£
Glassware, Chemicals, etc			250,000
Protein Fractionation Centre, Edinburgh (Estimate)			450,000
BTS - Triple blood packs etc for own use			400,000
Commercial blood products:			
Profilate	1,004,500 units	180,800	
Hyate	430,220 units	155,000	
* Feiba	2,806,000 units	841,700	
Cytotect CMV	6,800 mls	64,200	
Autoplex	134,000 units	40,300	1,282,000
			2,382,000
		Budget 1987/88	1,482,000
		Projected overspending	900,000

Figures shown for Protein Fractionation Centre, Edinburgh and commercial blood products are net of supplies to other Boards for which charges have been raised but as yet remain uncleared as follows:

			Fractionation	Commercial	Total
X	Southern Board	As at 31.3.87	43,128	29,489	72,619
		1.4.87-31.1.88	30,016	21,880	51,896
			73,144	51,369	124,513
X	Western Board	As at 31.3.87	32,048	4,260	36,308
		1.4.87-31.1.88	28,615	18,676	47,291
			60,663	22,936	83,599
	Northern Board	1.4.87-31.1.88	21,268	10,210	31,478
	Owing as at 31 January 1988		155,075	84,515	239,590

X Southern & Western Board are refusing to accept liability on the grounds that we were originally funded for all BTS costs.

THIS E. Board 0·130 x 12 0·900 0·150

PROFILE 13 BLOOD TRANSFUSION SERVICE.

~~Summary of Proposal:~~

The proposal is to run the Blood Transfusion Service within the resources allocation to it which for 1988/89 will be £2.95m.

1. The use of blood products such as Factor VIII and substitutes, plasma, albumin, platelets, etc would inevitably have to be restricted. These products are used by mainly clinicians throughout Northern Ireland and the indication for use is inevitably demand responsive. How, at what level, and by whom will limits be imposed?

2. Major surgery - cardiac, orthopaedic, cancer and plastic, leukaemia, bone marrow transplantation would all be affected. There would inevitably be a reduction in major planned work.

3. Blood and blood products would have to be made available for emergencies and obstetrics in life threatening situations.

4. Haemophilia uses a lot of blood products - mostly factor V. But 10% of Haemophiliacs develop an inhibitor. There are 11 such patients now, and factor VIII cannot be used. If the patient is to survive a bleeding episode treatment with an alternative is very expensive. A recent such patient cost £9,000 per day.

5. There seems to be no point in setting up "self-sufficiency" for Northern Ireland - this would be very costly. Existing arrangements should continue.

6. In general, the cost of medical technology, modern surgery and development of new drugs has far outstepped normal government funding.

- Complicated haemophillia
- 10% of all haemoph.
- Rising at ? rate p.a ?
- 1978 16 patients
  1987 11 patients }

12m