

4 (i)

SNBTS FORECAST DEVELOPMENT ESTIMATES 1984 - 1986

(Introductory comments by National Medical Director)

INTRODUCTION

- 1.01 Recent events within the Agency have re-emphasised the need for the Transfusion Service to reconsider ways in which its long range forecasting of financial expenditure can be improved. The document to which these introductory remarks refer represents the first attempt made by the SNBTS as a whole to meet not only the general need but also the specific timetables set by the Agency, SHHD and the Treasury.
- 1.02 It is the Directors' view that it might be helpful if the BTS Sub-Committee members were aware of the present difficulties. One of these can be appreciated by examination of the diagram at Appendix I.
- 1.03 It is the experience of the Directors that detailed Estimates for the forthcoming financial year which are eventually submitted to the BTS Sub-Committee, have a formal gestation period of at least 4 months within the SNBTS. This includes detailed discussions between senior staff within each operational unit followed by exhaustive discussions at meetings between all Directors and the National Administrator with the National Medical Director in the Chair. The existing appropriate final deadline for consideration by the BTS Sub-Committee (in order to permit consideration by the appropriate meeting of the Finance and General Purposes Sub-Committee (September)) is submission to CSA HQ by the last week in July, in order to be tabled at the August meeting of the Sub-Committee. At the present time details of the allocations for Developments do not emerge until June, or later - a time when Centre staff are about to go on holidays - yet current financial timetables demand a detailed response from the Service by the end of July for the forthcoming financial year. It should be emphasised that the Transfusion Service Division of the Agency has 7 separate Budget Holders.
- 1.04 The events over the past 3 months which have led up to the submission of this document have been painful: Transfusion Directors and their staff have had to contend with major impending changes in policy following the implementation of the Medicines Act, the continued and unchecked escalation in the demand for blood products, the absence of unequivocal guidance on the operational posture to be adopted towards commercial blood product manufacturers and/or retailers and what appear to be inevitable delays in receipt of information at Unit level on financial allocations after the beginning of a financial year. In summary, the Directors are having to contend with targets over a whole range of issues with clear operational guidelines and coupled with rigid timetables not evolved to meet the needs of the operational units. These difficulties are further compounded by the absence of access to/

to the type and range of skills which would enable the Directors to provide accurate costings on many of the future developments and, perhaps even more importantly, to have access to data which would permit them to consider options related to the cost benefit of the various services already provided or which they are requested to provide.

- 1.05 The SNBTS Directors would wish to place on record their thanks and appreciation to senior colleagues in the Administration and Finance Branches of CSA Headquarters Unit for their continued and considerable assistance since May 1981.

BRIEF RESUME

- .01 There are several areas in which developments are expected, between now and 1985/86 for which detailed policies have yet to be worked out. These can be listed as follows:-

(a) MEETING NEW DEMANDS IN BLOOD AND BLOOD PRODUCTS

- .02 (i) Blood and Regional Centre Derived Products & Services

X There are two significant developments emerging in this area: an increase in cardiac by-pass surgery and bone marrow transplantation. Both these clinical activities require substantial transfusion support. Despite the lack of co-operation from Health Boards an adequate account of the developments in cardiac surgery has now been included in the enclosed proposal. The problems of marrow transplantation are likely to be more complex and with a higher unit (patient) cost, and there is an urgent need for collaboration with Health Boards.

- 2.03 The BTS Sub-Committee is requested to ask the Management Committee to consider ways in which all Health Boards would be advised to include the Regional Transfusion Services in discussions related to the planning of marrow transplantation programmes. This support would include not only the provision of blood and blood products but, in some areas, tissue matching services.

- .04 (ii) Factor VIII and Albumin

Consideration is now being given by the SNBTS Directors to the consequences of discussions held with the Scottish Haemophilia Directors regarding the likely trend in the demands for factor VIII concentrates for the next decade. It is clear that with the existing clinical practices, there is unlikely to be a problem with the availability of albumin if the future requirements of factor VIII are met.

- 3.05 The BTS Sub-Committee may wish to note that a report with appropriate broad proposals will be tabled in due course. The basis/

The basis of the proposals will be two-fold: an 18-24 month (2 financial years) period in which funding will be required for a series of experiments designed to examine the most cost-effective and practical ways of enhancing fresh plasma procurement, followed by the routine introduction of one and/or both of the options studied in all Centres. This latter feature (which it is hoped will begin in 1984/85) will represent the commencement of the formal routine programme of the SNETS to meet the new targets for factor VIII production. Whereas the experimental period has not yet been costed it is estimated the formal routine programme will evolve over a period 1984/85 - 1989/90 (inclusive) and that each year will require an increase in revenue expenditure of approximately £350,000.

.06 (iii) Improved Quality Assurance of Existing Products Prepared at Regional Centres

Whilst considerable finance is being committed to quality assurance of products produced at PFC, this area of activity is rudimentary within the Regional Centres and will, at the behest of the Medicines Inspectorate, require considerable attention over the next 5 years. Funding will be required for staff (including clerical support) and laboratory facilities. The products concerned at the present time include whole blood, red cell concentrates, fresh frozen plasma, platelet concentrates, cryoprecipitate products, outdated plasma and hyperimmune plasma.

.07 The BTS Sub-Committee may wish to note that these matters will be placed for consideration by the Sub-Committee after the forthcoming visits of the Medicines Inspectors to the Regional Centres.

.08 (iv) New Product Range

Studies are in hand, and at various stages of evolution, with regard to the introduction of new products. These can be summarised as follows: intravenous immunoglobulins, high titre anti-tetanus immunoglobulin, low hepatitis risk factor IX concentrate, a new range of specific immunoglobulins directed towards coliform organisms, antithrombin III, fibronectin and high titre immunoglobulin preparations of existing products with particular reference to hepatitis B virus and cytomegalovirus.

.09 The Sub-Committee may wish to note that for most of these products initial development work is being funded from existing resources. However, in almost each case a project will reach a point when significant extra funding will be required in order to produce production batches for routine clinical use and/or the/

the mounting of clinical trials. Of no less importance is the fact that the current rate of progress in many of these areas is now controlled by the availability of existing research and development resources, and that this rate of progress may be inadequate to prevent penetration by commercial fractionators.

It should be noted that the cost of clinical trials required for any one product may be as much as £250,000 and that the SNBTS has no staff establishment for conducting clinical trials.

The BTS Sub-Committee are requested to consider what action should be taken with regard to the seeking of extra funding for a new range of blood products.

(b) DATA CAPTURE AND ANALYSIS

3.01 The SNBTS has been slow to initiate this development, primarily because it was agreed that the available funds over the last 5 years should be directed primarily towards increasing supplies of plasma for fractionation. It is now clear that the introduction of data capture and analysis systems is urgently needed, which is in line with other transfusion services throughout the Western world and in England and Wales. It is certain that the introduction of such systems will enhance donor management programmes, improve the ability of the SNBTS to comply with the demands of the Medicines Inspectorate and improve the overall management capability of the Service. It should be emphasised that the new range of donor grouping machines soon to be ordered presuppose that data capture/analysis systems will be available.

3.02 The BTS Sub-Committee may wish to note that an ISD/SNBTS Joint Working Party has been formed to delineate and implement an overall SNBTS programme for computer applications. It is hoped that the initial proposals for this programme should be finalised by December, 1982 and submitted to the BTS Sub-Committee as soon as possible thereafter.

(c) SNBTS BUILDING PROGRAMMES

3.01 The increased demands for blood and blood products and other services which have been met by the Regional Centres over the last decade have created significant deficiencies in the overall accommodation of all the Regional Centres. It is fortunate that in most of our Centres preliminary planning (advanced in some cases) has been established prior to visits by the Medicines Inspectors. This feature will provide the Inspectorate with evidence that at least as far as accommodation is concerned, the SNBTS is planning for the future. In this planning exercise/

exercise thanks is due to Dr Charles Camm of the Building Division. The present state of the various building programmes is summarised on the attached Appendix II.

4.02

The BTS Sub-Committee may wish to note that there will be significant increases in revenue expenditure associated with what amounts to a rolling programme of capital (building) works for the SNBTS over the next 5-10 years. Of particular quantitative importance will be the consideration of building a new Centre in the West of Scotland, and the building associated with PFC's response to the Medicines Inspectorate.

(d) NEW HEPATITIS TESTING DEVELOPMENTS

5.01

It is anticipated that technical developments will have reached a point within the next 5 years that the introduction of the testing of all donations for non-A/non-B hepatitis markers or associated markers will be mandatory.

5.02

The BTS Sub-Committee may wish to note this probable development. If it is assumed that current reagent costs for hepatitis B antigen testing will apply to reagents for non-A/non-B and it is assumed that non-A/non-B is one virus (almost certainly more than one), then the likely minimum increase in revenue cost for this development within the SNBTS will be in the region of £150,000 p.a. (285,000 x 50p). Recent published studies would indicate that a figure of £300,000 is likely to be more realistic (two further tests on each donation).

(e) CONSEQUENCES OF MEDICINES INSPECTORATE ACTIVITIES

6.01

Following constructive discussions with colleagues at CSA HQ concerning the events which took place subsequent to the inspection of PFC, it has been decided to review and submit to the BTS Sub-Committee, Centre by Centre, the requirements needed to satisfy the Medicines Inspectorate. The Inspectorate have expressed serious concern at the slowness of the Agency's response to the PFC Report and, in order to speed up the process of assessing the financial consequences of the Reports, it is proposed that in future the review will be undertaken by staff of CSA HQ, SNBTS HQ and each Centre, with a view to completion and submission to the BTS Sub-Committee within 6 months of receipt of the Inspector's Report.

6.02

The BTS Sub-Committee are asked to endorse this proposal and to request the Management Committee to invite the Secretary of the Agency to advise the Medicines Inspectorate (DHSS) to send a copy of their Report for each Centre directly to CSA HQ at the same time as it is issued to the SHHD.

October 1981

Secretary calls for estimates and development proposals for 1983-84 and forecasts for 1984-85 and 1985-86 to be submitted to him by 31st December.

October 1981

Transfusion Centres prepare their outline proposals for 1983-84 and forecasts for the 2 succeeding years.

November 1981

Transfusion Centres submit their outline proposals for 1983-84 and forecasts for succeeding years for consideration by BTS Co-ordinating Group.

November/December 1981

BTS Co-ordinating Group consider outline proposals for 1983-84 and forecasts for 1984-85 and 1985-86, and agree outline submissions.
Probably two meetings needed.

January 1982

BTS submit outline proposals for 1983-84 and forecasts for 1984-85 and 1985-86 for consideration by BTS Sub-Committee.

February 1982

BTS Sub-Committee consider outline submissions for 1983-84 and forecasts for 1984-85 and 1985-86 and make recommendations to F and GP Sub-Committee.

March 1982

F and GP Sub-Committee consider outline proposals and forecasts from BTS Sub-Committee and make recommendations to Management Committee.

March 1982

Management Committee consider F and GP Sub-Committee's recommendations and approve certain proposals.

March 1982

CSA forwards proposals to SHHD for funding.

February/March 1982

Transfusion Centres prepare detailed cases for 1983-84 proposals and forecasts for 1984-85 and 1985-86 for consideration by BTS Co-ordinating Group.

April 1982

BTS Co-ordinating Group approve final detailed proposals for 1983-84 and submit them to CSA Secretary.

May 1982

BTS Sub-Committee consider final detailed proposals for 1983-84 and give approval in principle.

June/July 1982

Development allocations for financial year 1982-83 made available to SNBTS.

July 1982

Co-ordinating Group meet to list priorities for 1983-84 in the light of allocation for 1982-83.

August 1982

BTS Sub-Committee reconsider final detailed proposals for 1983-84 in light of allocations made in June/July for 1982.

September 1982

Finance and General Purposes Sub-Committee consider development proposals for 1983-84 in detail and make recommendations to Management Committee.

September 1982

Management Committee consider F and GP Sub-Committee's recommendations and approve development proposals for 1983-84.

September 1982

Management Committee submit detailed proposals to SHHD for funding from 1st April, 1983.

October 1982

CSA Secretary calls for estimates and development proposals for 1984-85 and forecasts for 1985-86 to be returned to him by 31st December.

| Centre | | Centre Studies in progress | SNSTS Directors' Approval | BTS Sub-Committee Approval | Personnel & Accom. Sub-Committee Approval | Building Division Design Team Established | Project Costed & Approved | Project to Tender | Completion and Commissioning |
|----------------|-------------------|----------------------------|---------------------------|----------------------------|---|---|---------------------------|-------------------|------------------------------|
| ABERDEEN EXT. | | Yes | Yes | Yes | Yes | Yes | No | No | |
| DUNDEE EXT. | | Yes | Yes | Yes | Yes | No | No | No | |
| EDINBURGH | Phase I | Yes | Yes | Yes | Yes | Yes | Yes | Yes | ? July 1982 |
| | Liv. Ho. Ext. | Yes | Yes | Yes | Yes | Yes | Yes | Yes | ? |
| | Main Ctr. Refurb. | Yes | No | No | No | No | No | No | No |
| GLASGOW | Blood Comp. Ext. | Yes | No | No | No | No | No | No | No |
| | New Ctr. | Yes | No | No | No | No | No | No | No |
| INVERNESS EXT. | | Yes | No ⁽¹⁾ | No | No | No | No | No | No |
| P.F.C. EXT. | | Yes ⁽²⁾ | No | No | No | No | No | No | No |

(1) Due to be tabled at Co-ordinating Group (23rd February, 1982) meeting.

(2) Work currently underway in association with Building Division and TPH HQ staff.