ADVISORY COMMITTEE ON THE NATIONAL BLOOD TRANSFUSION SERVICE

I. STRUCTURE OF THE BLOOD TRANSFUSION SERVICES IN THE UNITED KINGDOM

England and Wales

- Each of the Regional Health Authorities in England is responsible for meeting the transfusion requirements of its hospitals and, with the exception of the South East and South West Thames Regions, which share, each Region has its own Transfusion Centre. In Wales there is a Transfusion Centre at Cardiff.
- 2. The Regional Transfusion Centres' main tasks are to recruit donors and to collect group test and issue blood, to make red cell, white cell and platelet preparations; to separate plasma and send it to the Blood Products Laboratory for processing; to manufacture one form of Factor VIII (the unconcentrated cryoprecipitate); to provide a consultancy service for the Region on all blood transfusion matters; and in some Regions to undertake tissue typing in connection with organ transplantation and to provide a Regional .ank - nated Service.
- 3. There are three Central Blood Laboratories which are centrally financed and which are run jointly on an interim basis, by the North West Thames Regional Health Authority and the Department. The ultimate management structure for the Central Laboratories has still to be decided.
- 4. The Blood Products Laboratory at Elstree (124 staff) manufactures :
 - (a) Factor VIII concentrate (for the treatment of haemophiliacs) and other coagulation factor concentrates;
 - (b) Various preparations of Albumin (inparticular plasma protein fraction, PPF) which are mainly used for therapeutic plasmapheresis and in the treatment of burns etc;
 - (c) A range of specific and normal immunoglobulins (for example anti-D immunoglobulin) for the treatment of Rhesus disease in babies and antitetanus immunoglobulin;
 - (d) It also carries out research and developments on blood products.
- 5. The Plasma Fractionation Laboratory at Oxford (26 staff) manufactures the Factor VIII concentrate required in the Oxford Region and most of the Factor IX (for the treatment of patients with Factor IX deficiency or Christmas disease) used in the NHS. There are plans to incorporate the work of the PFL at Elstree.
- 6. One of the main problems facing the Blood Transfusion Service is that the service does not have the fractionation capacity to produce sufficient blood products to achieve national self-sufficiency and as a result, Health Authorities have to purchase blood products (valued at £10 m per year) from commercial sources..
- 7. Following an inspection by the Department's Medicines Inspectors last year, Ministers have agreed that a programme of short term improvements to the laboratory should be put in hand. The proposed short-term upgrading will provide better facilities and allow production to be increased - Factor VIII by 100% and Albumen containing products by 60%.
- 8. In the long term, it is intended to replace the laboratory by a new fractionating facility to be built either within the NHS or in collaboration with British Industry. The aim will be to build a factory, which, together with expanded production at the PFC Edinburgh, will be capable of meeting the national requirements for blood products.

44/310

9. The Blood Group Reference Laboratory currently at Chelsea (37 staff);

- (a) acts as a reference laboratory for NHS blood grouping problems and participates through WHO in European arrangements for providing some rare groups of blood and maintains a panel of donors of rare blood types.
- (b) manufactures some blood grouping sera for the NHS;
- (c) monitors blood grouping in the NHS.
- 10. The laboratory is currently housed in premises in the Chelsea Bridge Road which belonged to the Lister Institute until their sale to a development company in May of this year. The BGRL is to move to the Harkness Building in Oxford inJanuary 1982, by which the time the building will have been re-furbished. Developments in the field of monoclonal antiobody production may lead to a significant expansion in the BGRL's activities as a producer of blood grouping anti-sera for the NHS.

Scotland

- 11. The Scottish National Blood Transfusion Service has 5 Regional Transfusion Centres, and the Protein Fractionation Centre (PFC) in Edinburgh manufactures its blood • products.
 - Northern Ireland
- 12. Northern Ireland Blood Transfusion Service has 1 Transfusion Centre in Belfast. Plasma (currently only time expired) is sent for fractionation to the Blood Products Laboratory.
- II. THE NEED FOR AN ADVISORY COMMITTEE ON THE NBTS
 - 13. In 1975, a Central Committee for the NBTS was set up with the following terms of reference :-
 - " To keep under review the operation of the National Blood Transfusion Service, including the Blood Products Laboratory and the Blood Group Reference Laboratory in England and Wales and to advise the Department of Health and Social Security and the Welsh Office on the development of these services."
 - 14. The Committee was chaired by a Senior Departmental Medical Officer and had 16 members which included 2 Regional Transfusion Directors, 2 Regional Medical Officers and 1 Regional Scientific Officer. The remaining members represented each of the following disciplines:-

General Practice. Anaesthesia. Surgery. Medicine. Pathology. Obstetrics. Nursing & Medical Research.

15. However, because of the Committee's size, breadth of membership and very general terms of reference it was unable to provide the advice the Department needed. No meetings have been held since the Autumn of 1978 and the Committee is now to be formally disbanded.

44/311

Advisory Committee on the NBTS

- 16. The developments which have occurred in recent years in blood transfusion practice, the increasing requirements for adequate supply of products derived from blood (e.g Factor VIII and Albumin) and the need to ensure supplies of plasma for the BPL, call for greater co-ordination of the development and activities of the Regional Transfusion Centres and the Central Blood Laboratories in England and Wales, and for better liaison with the Scottish National Blood Transfusion Service and the Northern Ireland Blood Transfusion Service.
- 17. Through their chairman, Dr Tovey, Consultant Adviser in Blood Transfusion, Regional Transfusion Directors proposed to the Department that a new Advisory Committee on the NBTS should be established to replace the former Central Committee for the NBTS, In agreeing with this proposal, the Department considered that such a Committee should be smaller than the former one and membership should be restricted to those most closely concerned with the Blood Transfusion Service and Health Authorities.
- 18 The Committee's terms of reference are:-

" To advise the Department of Health and Social Security and the Welsh Office on the co-ordination of the development and work of Regional Transfusion Centres and the Central Blood Laboratories in England and Wales and, as necessary - the English and Welsh Blood Transfusion Service with that of Scotland."

- 19. The following are the main Committees with which the Advisory Committee's work will be linked:-
 - (a) The Scientific and Technical Committee of the Central Blood Laboratories

This committee is concerned with the scientific and technical development of the Central Laboratories. An ad hoc group, the Technology Working Group, have recently examined the question of potential fractionation technology which a new facility will need.

(b) The Joint Management Committee

The Joint Management Committee (DHSS/North West Thames RHA) for the Central Blood Laboratories was set up in December 1978 to oversee the running of the Central Laboratories.

The Finance Sub-Committee of the JMC examines the laboratories' budgets and other financial questions.

(c) Advisory Group on Hepatitis

This Group was set up to examine the many problems in relation to viral hepatitis and its management. In relation to the NBTS, it will be considering the problems of staff and donors found to be hepatitis B carriers.

III. AN OUTLINE OF SOME OF THE MATTERS RELATING TO THE NETS ON WHICH THE DEPARTMENT WILL NEED TO SEEK ADVICE

- i. BLOOD PRODUCT DEMAND:
 - What is the current NHS usage of blood products of all kinds and from all sources?
 - What is the forseeable demand for each type of product?

3

44/312

- What are the factors bearing on this demand and could they be modulated?
- Should different purchasing policies and methods of distribution of blood products be instituted?

ii. PLASMA SUPPLY:

- What percentage of donations should be used to provide fresh, frozen plasma (FFP)?
- How can uniform standards for plasma quality be adopted?
- How can the FFP supply be expanded to coincide with the BPL's new production targets?
- Could the quantity of FFP needed to meet forecast levels of self sufficiency in blood products ever be achieved?
- What methods should be used to meet some or all of the forecast plasma requirements.
- How could the varying plasma- generating capacities of different Regions be reconciled, in order to make best use of resources.
- What are the likely building, staffing, equipment and other consequences to Regional Transfusion Centres of the expansion of plasma collection to the required levels?
- How should the plasma collection programme be financed?

iii. PLASMA FRACTIONATION:

- Can better use be made of the present facilities in England and Wales?
- Can uniform standards for product specification be adopted?
- How may the proposed scheme of pro-rata distribution of blood products (see paper AC (80)5) be implemented in relation to the needs of special units?
- Assuming the provision of a new fractionation plant in England how should the required output be divided between the English and Scottish plant?
- What type of management structure would be most appropriate for the English laboratory?

- 4 -

44/313

CBLA0001208 0004

iv. SURPLUS BLOOD PRODUCTS AND COMPONENTS

- What should be done with the current and forecast surplus products of fractionation which are not needed by the NHS.
- How may it be possible to collaborate with industrial and research establishments in the provision of surplus blood components (see Appendix) without prejudice to the voluntary donor system?

v. AUDIT OF BLOOD USAGE:

- How may a greater check be kept on the use to which blood is put after it leaves RTC s?

vi. FINANCIAL ARRANGEMENTS

- how should an expanded plasma collection programme be financed?
- how should redevelopment of the BPL be financed?
- should the supply of plasma to BPL and the supply of products to Authorities be the subject of financial adjustments between BPL and, Authorities, and if so, on what basis?
- what financial arrangements should be made in respect of surplus products ((iv) above)?

- 5 -

44/314

APPENDIX -

PROVISION OF COMPONENTS AND PRODUCTS FOR DEVELOPMENTS OUTSIDE THE NHS

i. <u>Interferon</u>

This drug, which is still in the research stage as a treatment for cancer and certain virus illnesses may, at present, be produced in two ways either from bulk cells (i.e leucocytes or white blood cells or from tissue culture). It is likely to be produced by genetic engineering techniques in the future. White blood cells can be harvested at Transfusion Centres but it is a costly and time consuming process and very large quantities of white blood cells are required to produce a very small amount of interferon. The drug is being used in clinical trials to establish its efficacy and research is going on to ascertain the best way of manufacturing it.

It is possible that the Scottish National Blood Transfusion Service may set up a unit to manufacture leucocyte interferon from buffy coats derived from Scotland and, perhaps, one or two Regions in England. If this unit cannot be set up, there will be no source of leucocyte interferon for clinical trials in the UK.

A commercial company has recently approached the DHSS with a scheme to manufacture leucocyte interferon from NBTS buffy coats.

ii. Haemoglobin - Dextran "Artificial Blood"

A compound with oxygen carrying capacity is being developed by a commercial firm as a blood substitute. Its manufacture requires large quantities of out-dated red cells. The company has approached the DHSS about obtaining out-dated red cells from the NBTS.

44/315