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PRODUCTION OF BIOLOGICALS (PHASE I), A SURVEY

UC/RAS/83/234

Technical report: The supply of blood products in the ASEAN countries*

Prepared for the Governments of Indonesia,
Malaysia, Singapore, Thailand, The Philippines
by the United Nations Industrial Development Organization

Based on the work of P. Schiff
Expert in production of human blood products

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INTRODUCTION

As part of a survey on the production of biologicals (Phase I) by UNIDO, the Commonwealth Serum Laboratories in Australia agreed to provide three experts to evaluate and report on the production of insulin, blood products and vaccines in the ASEAN countries (Malaysia, Singapore, Indonesia, Thailand and the Philippines). I was appointed as the expert in the production of blood derivatives and also in the collection of blood and raw materials for plasma fractionation and undertook my mission during June/July of 1985.

The background to this mission was as follows. In late September 1982, a seminar was held in Stockholm, Sweden under the auspices of UNIDO and the Committee for National Cooperation on Pharmaceuticals of the Ministry of Health and Social Affairs, Sweden together with the WHO and the League of Red Cross Societies on "National Self-Reliance in Blood and Blood Fractions for Developing Countries". The aim of this conference was to acquaint representatives of developing countries with the various facets of blood transfusion services and the industrial scale plasma fractionation. Among the recommendations included in the plan of action at this seminar were that UNIDO should carry out a survey of existing facilities, infra-structure and availability of plasma for fractionation in developing countries and assist in transfer of technology for establishing/expanding/improving plasma fractionation on laboratory/pilot/industrial scales. UNIDO could provide assistance in training of personnel for the production of blood derivatives.

It is generally recognised that blood is a vital national resource and that each country should strive to be self-sufficient as far as the supply of blood and blood products for its citizens are concerned. While this is generally true for most developed countries, although there are notable exceptions (eg the supply of Factor VIII), the situation is far from ideal in many developing nations. Patients either have to do without products which, in many instances, are life-saving or they may be imported in limited quantities and often at great cost both to the individual concerned and to the national economy.

The purpose of this mission, therefore, was to visit five countries in the South-East Asian region to examine their Transfusion Services including present and potential capacities, to discuss the need for blood and blood products with clinicians who would normally be expected to administer them, eg haematologists, anaesthetists and emergency care physicians and to seek the views of Health Ministries on the relative importance of these forms of therapy and their priority in the overall health care picture.

Some two months before setting out on this mission, I had pre-circulated to Directors of Transfusion Services and Ministries of Health, a questionnaire entitled 'Supply of Blood and Blood Products Questionnaire", a sample copy of which is attached to this report (Appendix 1). The information contained in these

questionnaires, together with further data that I gleaned by personal interviews, forms the basis of my report for each country visited. Although the set of questionnaires returned was not complete, I have attached copies of those received at the end of each relevant section so that readers may judge for themselves whether my interpretation of the data has been accurate.

In the following sections I intend to report as fairly and objectively as I can the situation which now exists in the various countries that I visited. I shall clearly indicate where I was confronted with differences of opinion or where I have added opinions or conclusions of my own. Each of the next five sections will deal with one of the ASEAN countries and this will be followed by a general discussion. Finally, I shall summarise the entire report and make some recommendations.

SUPPLY OF BLOOD & BLOOD PRODUCTS QUESTIONNAIRE

1. Name of country

2. Population

   (a) Total

   (b) % living in major cities & regional centres (numbers ≥50,000/centre)

   (c) % rural dwellers.

3. Describe briefly existing blood transfusion services

   (a) Centralised blood banks

   (b) Hospital-based blood banks

   (c) Mobile blood collection services

   (d) Regional distribution networks

   (e) Other

4. Blood donation

   4.1 Total number of donors

   4.2 Classification of donors

      4.2.1 Number of voluntary unpaid donors

      4.2.2 Number of voluntary paid donors

      4.2.3 Number of professional donors

      4.2.4 Others

4.3 How many donations are collected annually and used as :

(a) whole blood

(b) red cell concentrates

(c) plasma (give volume in litres).

If plasma is obtained other than as a by-product of red cell concentrates e.g. by plasmapheresis, indicate the additional volume collected annually (in litres).

4.4 Which of the following organisations are responsible for blood collection in your country? Indicate percentage that each contributes to the overall collection.

4.4.1 Nationally funded and controlled blood banks %....

4.4.2 Blood banks belonging to other organisations e.g. Red Cross %....

4.4.3 Commercial blood banks %....

4.4.4 Others %....

4.5 List the biomedical tests performed on donors (please tick)

4.5.1 Chemical

Haemoglobin estimation ...
Serum protein level ...
Serum iron ...
Serum bilirubin ...
Other (specify) ...

4.5.2 Biological

Syphilis ...
Hepatitis B ...
Malaria ...
AIDS ...

4.6 Transmissible disease among donors (state their frequency) :

4.6.1 Hepatitis B

4.6.2 Malaria

4.6.3 Other parasituses (specify)

4.6.4 AIDS

4.6.5 Others (specify)

5. Production of non-stable (cellular) derivatives

5.1 Indicate for the following products the quantities collected/prepared and used :

		Collected/Prepared	Used
5.1.1	Whole blood		
5.1.2	Red cell concentrate		
5.1.3	Frozen fresh plasma		
5.1.4	Dry plasma		
5.1.5	Platelet concentrate		
5.1.6	White cell concentrate		
5.1.7	Others		

5.2 Indicate the imported and exported quantities of the abovementioned products and the origin of the imports.

6. Production of stable derivatives

6.1 Indicate for the following products the quantities produced and used :

		Proposed	Used
6.1.1	Albumin (including PPF or SPPS)*		
6.1.2	Factor VIII		
6.1.3	Factor IX		
6.1.4	Immunoglobulins (a) Normal		
	(b) Specific		
6.1.5	Other		

6.2 Indicate the imported and exported quantities of the abovementioned products and the origin of the imports.

6.3 Quantity of plasma collected annually.

6.4 Quantity of plasma fractionated annually and by whom.

* PPF Plasma protein fraction
SPPS Stable plasma protein solution

7. Reagents used in immunohaematology

7.1 Indicate the type of reagents and the quantities used annually.

7.2 Indicate the quantities of these reagents produced in the country by type and volume, e.g. anti-A typing serum 50 litres, etc.

7.3 Indicate the serological assessment which blood donors undergo and the origin of the reagents used.

7.4 Indicate serological assessment which recipients undergo and the origin of the reagents used.

8. Use of blood and blood products

Describe briefly the regulations in effect in the country regarding the use of the principal products.

8.1 Who are the major distributors and users of blood products for diagnosis and therapy?

9. Blood transfusion costs

(Include costs incurred by Blood Transfusion Services and Government subsidies where appropriate)

9.1 Gross cost

9.2 On the basis of total health program costs, indicate the proportion represented by blood transfusion programs.

10. Treatment of patients suffering from haemophilia

10.1 Indicate the products used in the treatment of patients suffering from haemophilia.

10.2 Indicate the annual cost of the treatment of patients suffering from haemophilia.

11. Bases of co-operation

Indicate your country's requirements with respect to blood derivatives and any interest that may exist in co-operation with other countries in this area.

12. Projects of the country

12.1 Indicate the country's projects in the area of blood donation

12.2 Indicate any projects the country may have, at the national or regional level, regarding industrial blood-fractionation facilities

MALAYSIA

In Kuala Lumpur, I met and had discussions with the following -

Dr. C.G. Lopez - Director, National Blood Services Centre, General Hospital, Kuala Lumpur

Dr. Jones Verughese - Director, Hospital Services Division, Ministry of Health

Dr. Lim - Deputy Director, Hospital Services Division, Ministry of Health

Dr. Chong - Deputy Director, Institute for Medical Research

Mr. Liew - Director, Pharmaceutical Division, Ministry of Health

Mr. Che - National Pharmaceutical Control Laboratory

Mr. Khoo - Chief Pharmacist, General Hospital

Dr. Looi - Head, Department of Pathology, University Hospital

Drs. Maneka, Kuperan & Cherian - Heamatologists, University Hospital

In 1984, Malaysia had an estimated population of 15.279 million comprising Malays, Chinese, Indians and several other races. Of these, 12.6 million live in Peninsula Malaysia, 1.4 million in Sarawak and 1.2 million in Sabah.

In Malaysia, almost all the blood banks are attached to Government hospitals, ie the organisation is fundamentally hospital based and hospital controlled. There are 60 hospitals in Peninsula Malaysia and 32 hospitals in East Malaysia. Thirteen of these hospitals may be designated as having regional blood banks. The National Blood Services Centre launched in April 1972 is itself part of the General Hospital, Kuala Lumpur. It was set up as "an independent body sited at the Blood Services Centre, Hospital Besar, Kuala Lumpur integrating all Government hospital blood bank services in the country including the serving of Hospital Besar with proper staff and facilities under the Hospital Division of the Ministry of Health".

Apart from the normal transfusion services, specialised haematology services are also provided by the Blood Services Centre to the General Hospital. This linkage of transfusion services with haematology proved to be advantageous providing a better understanding of transfusion needs for patients and unique opportunities for medical officers and technologists for comprehensive and meaningful training in both transfusion and haematology in the same premises. The speciality of blood transfusion is not generally considered an attractive posting for Malaysian doctors. The development of an emphasis on the clinical aspect of blood transfusion has therefore played an important role in attracting suitable medical officers for the Service and will continue to provide a suitable training environment in all aspects of transfusion and haematology in the country for future specialists.

The early history of blood transfusion practice in Malaysia geared the Services towards a voluntary non-remunerative system and most blood banks attempted to recruit donors based on these principles. Furthermore, a national policy for a non-remunerated system for donor recruitment was formalised in 1979 when the first national seminar for transfusion services was held. Some of the aims and goals laid down at this seminar were as follows -

1. To encourage, foster and support efforts to form a totally voluntary non-remunerative blood donation system.

2. To achieve a target of ten percent adult urban or two percent of the general population in donor recruitment in all States in Malaysia. Under this system, mobile and group donations were to be increased.

3. Greater centralisation of donor recruitment was to be brought about to prevent unnecessary competition for donors, particularly in the main cities.

4. Replacement donors were to be gradually abolished. Mobile and group donations were to be increased.

5. Component therapy was to be increased and whole blood transfused reduced progressively to not more than 20 percent.

There has been a steady, if slow, increase in the total number of blood units collected in Malaysia. Thus, the total collection for 1983 of 131,650 units compares with a figure of 127,869 units for the year before. This represents an average figure for the country as a whole of 10 per 1000 inhabitants or one percent of the total population.

It has been estimated that the basic blood requirements of a hospital can be equated to the number of acute care beds. Thus, to cope with the needs of 1000 such beds, a donor panel of some 7000 individuals is required. As there are some 27,000 Government hospital beds in both Peninsula and East Malaysia, at least 189,000 units of blood would be required. It has also been stated that the needs for blood can be satisfied if some two percent of the population are regular donors. On this basis, some 304,000 donations annually would be required to meet the needs of a population of 15.2 million.

The quality and adequacy of transfusion services can also be gauged from the availability of blood products for patients requiring regular replacement therapy, eg Haemophilia A. It is estimated that Malaysia has some 650 patients with this disorder and for adequate management one should provide some 20,000 IU*of Factor VIII per patient per annum. This need to produce 13 million units of Factor VIII annually would require the processing of 130,000 units of plasma for the production of cryoprecipitate assuming that 100 units of Factor VIII can be extracted from each unit of blood. If consideration is to be given to the production of lyophilised concentrates for the

*International Unit

treatment of these patients then even larger volumes of plasma will be required as the recovery of Factor VIII C*activity is correspondingly reduced when intermediate or high purity concentrates are produced.

There are already some indications that greater quantities of blood than the national average can be collected. Thus, the number of blood units collected in the area served by the University Hospital in 1983 amounted to 3.2% of the population serving that area and 50-60% of the blood collected at the Blood Services Centre is currently being separated into components. If other centres were to follow these examples, both the total quantity of blood collected and the amount of plasma that could be made available for other purposes would increase significantly.

Although Malaysia has had a designated National Blood Transfusion Centre since 1972, it is synonymous with the General Hospital's Blood Transfusion Service. The hospital consists of 2500 beds, serving virtually all medical specialties and its demands on the Transfusion Service must be given priority. There are plans to build a new National Blood Transfusion Centre. This will be physically separate from the existing Blood Bank and preliminary plans have been developed but the site has yet to be selected. Although approved as a fourth Malaysia Plan project it did not proceed due to financial constraint and other priorities. It is included in the fifth plan and has gone forward with the Ministry's approval for consideration by an inter-departmental consultative committee. It may yet be shelved again, for according to Dr. Lim it is one of approximately 1000 surviving health projects and the total expenditure proposed of $M1.4 billion will need to be cut by about 50 percent. Dr. Jones subsequently confirmed that funds to commence the project will not be available before 1987 at the earliest. Current cost estimates range from 5.0 to 6.4 million ringgits (figures that may be unrealistically low). Staff will total 135 including 12 medical officers.

Dr. Lopez is trying to encourage the use of blood fractions. At present, 60 percent of blood collected is issued as concentrated red cells, the plasma being used either as fresh frozen plasma or for the manufacture of cryoprecipitate. Although Dr. Lopez estimates that there are 600-650 haemophiliacs in the country, only 250 are currently receiving regular treatment at the national centre. This consists mainly of cryoprecipitate but they do purchase some 500 x 250 IU vials of Factor VIII annually at a cost of $M110-120 per vial. Other blood products such as Albumin, Plasmanate and Immuno-globulins are not handled by the Blood Bank. They are handled as normal drugs and purchased through the hospital pharmacy. The Blood Transfusion Service staff is not consulted about their use.

Dr. Lopez believes that if a fractionation or component preparation centre is established, it should be run by scientific officers. These people have completed a three year university course majoring in a relevant science discipline (biochemistry, microbiology) and with a tertiary qualification. At present, there is a tremendous hiatus between the Director and Deputy Director and Laboratory Technicians

*Concentrate

who are neither trained to trouble-shoot or to interpret border-line results. Although there are five other medical officers currently assigned to the Centre, none want to make blood banking their career. The glamour discipline in pathology is histopathology and laboratory haematology evinces very little interest or status.

From Mr. Liew I learnt that WHO has also proposed a regional programme for the production of blood products in the Western Pacific region. UNIDO's interest appears to lie in its programme of increased industrialisation for developing countries and I therefore presume that the goals of the two UN bodies are complementary.

Mr. Khoo stated that Malaysia currently uses some 25,000 bottles of plasma volume expanders annually. I do not know the exact breakdown between Albumin, PPF and Haemaccel but from the University Hospital Pharmacy I learnt that they are currently paying $M70 for a 10 gram vial of 25% Albumin and $M17 for a 500 ml container of Haemaccel.

The intensive care unit at the General Hospital is swinging back towards blood products as they believe them to be superior for the management of shock in previously ill patients.

University Hospital, Kuala Lumpur is an 850 bed general hospital that is the main teaching hospital for the University of Kuala Lumpur Medical School. Their demand for blood products is governed by their need for platelets. They have a large clinic of haematologic malignancies particularly leukaemias that require platelet support. They also produce cryoprecipitate for the management of their haemophiliacs on a group specific basis when possible.

They have a definite need for Albumin-containing products, eg Plasmanate, as they do a lot of plasma exchanges but are able to replace only one-third of the volume removed with protein containing solutions. They are unable to support post-cardiac surgery patients or those with liver and renal diseases adequately because of a lack of Albumin. They simply cannot afford to purchase the quantities required. Haemaccel is being used as a plasma volume expander but is not a suitable replacement solution when proteins are required as in the conditions listed above.

Dr. Maneka felt that ability to produce a freeze-dried cryoprecipitate could be helpful, particularly if several units could be pooled before freeze-drying as this would simplify storage and transportation of the material to outlying areas.

Dr. Jones Verughese felt that the establishment of a separate national transfusion centre would be a prerequisite to the recruitment of additional donors. Extra staff, equipment and more vehicles for mobile visits would also be required. While I sensed that he was not unsympathetic to the idea of an ASEAN cooperative venture, how such cooperation could be implemented remains to be solved. If it was agreed that a fractionation plant should be built in the region, where would it be sited and who would be responsible for its management. In our round table discussion at the Institute for Medical

Research. Dr. Lopez commented that no parallel discussions on a proposed cooperative venture had yet taken place between the Directors of the relevant Transfusion Services. This is an important point as the relevant technical experts must first be convinced of the desirability and advantages of such a proposal which they can then explain to their respective Health Ministries.

SUPPLY OF BLOOD & BLOOD PRODUCTS QUESTIONNAIRE

1. Name of country Malaysia

2. Population

	Pen. Malaysia*	Sarawak	Sabah
	10,944,844	1,235,553	955,712

(a) Total 13.14 million

(b) % living in major cities & regional centres (numbers ≥50,000/centre)

	4,073,105 (40%)	222,529 (17%)	196,774 (20%)
(c) % rural dwellers	(60%)	(83%)	(80%)

3. Describe briefly existing blood transfusion services

(a) Centralised blood banks

(b) Hospital-based blood banks (1) Ministry of Health: 60 hospitals in Pen. Malaysia, 32 hospitals in East Malaysia, 13 regional blood banks. (2) Private Hospitals

(c) Mobile blood collection services
Each hospital blood bank has their own mobile unit deployed from existing permanent staff.

(d) Regional distribution networks

Generally poor. Each blood bank is responsible for their own collection. Exchange of blood is practical and some coordination of activities is still possible.

(e) Other

4. Blood donation

(1983)	Pen. Malaysia	Sarawak	Sabah	Total
4.1 Total number of donors	104,652	12,793	16,150	133,595

4.2 Classification of donors

4.2.1 Number of voluntary unpaid donors National Policy is Voluntary Non-Remunerated
4.2.2 Number of voluntary paid donors Not known
4.2.3 Number of professional donors Not known
4.2.4 Others (Replacement Donors 47,707 = 35%)

* Pen - Peninsula

4.3 How many donations are collected annually and used as:

(a) whole blood — 40% at Blood Services Centre. Up to 90% in other places.

(b) red cell concentrates 60% at Blood Services Centre, K.L.*

(c) plasma (give volume in litres). 969 litres at Blood Services Centre - no information available from other hospitals.
If plasma is obtained other than as a by-product of red cell concentrates e.g. by plasmapheresis, indicate the additional volume collected annually (in litres).
Nil by plasmapheresis.

4.4 Which of the following organisations are responsible for blood collection in your country? Indicate percentage that each contributes to the overall collection.

4.4.1 Nationally funded an controlled blood banks	% 90
4.4.2 Blood banks belonging to other organisations e.g. (Private Hospitals)	% 10
4.4.3 Commercial blood banks	%Nil
4.4.4 Others	%Nil

4.5 List the biomedical tests performed on donors (please tick)

4.5.1 Chemical

Haemoglobin estimation	X
Serum protein level	...
Serum iron	...
Serum bilirubin	...
Other (specify)	...

4.5.2 Biological

Syphilis	X
Hepatitis B	X
Malaria	Not done
AIDS	Survey this year. Next year probably routine.

4.6 Transmissible disease among donors (state their frequency):

4.6.1 Hepatitis B	Yes 3.0 - 4.0%
4.6.2 Malaria	Rare
4.6.3 Other parasitoses (specify)	Nil
4.6.4 AIDS	Possible but not so far found in high risk group
4.6.5 Others (specify)	Probable Hepatitis type NA NB and CMV

* Kuala Lumpur

5. Production of non-stable (cellular) derivatives

5.1 Indicate for the following products the quantities collected/prepared and used: at Blood Services Centre, K.L.

	1 year Collected/Prepared	1 year Used
5.1.1 Whole blood	1,500 bags	1,500
5.1.2 Red cell concentrate	13,500 bags	13,500
5.1.3 Frozen fresh plasma	2,700 bags	2,600
5.1.4 Dry plasma	-	-
5.1.5 Platelet concentrate	1,500 bags	1,500
5.1.6 White cell concentrate	33	33
Cryoprecipitate	9,600	9,500
5.1.7 Others		
Cryosupernatant	6,800 bags	5,200

5.2 Indicate the imported and exported quantities of the above mentioned products and the origin of the imports.

6. Production of stable derivatives

6.1 Indicate for the following products the quantities produced and used: (all hospitals).
No accurate records available and many of the products may be purchased by hospitals at requests of clinicians and not at central level.

		Proposed	Used(approx)
6.1.1	Albumin (including PPF or SPPS)		3,000 bottles
6.1.2	Factor VIII		500 vials x 250 125,000 units
6.1.3	Factor IX		108,000 units
6.1.4	Immunoglobulins (a) Normal		400 vials
	(b) Specific Rh Immunoglobulin		(?)100
6.1.5	Other - Fibrinogen		500 gram

6.2 Indicate the imported and exported quantities of the abovementioned products and the origin of the imports. 6.1. Fenwal/Travenol; 6.1.2 & 6.1.3 Cutter; 6.1.4 Variable; 6.1.5 Ortho(usually).

6.3 Quantity of plasma collected annually. -

6.4 Quantity of plasma fractionated annually and by whom. Nil

7. Reagents used in immunohaematology

7.1 Indicate the type of reagents and the quantities used annually.
Please see attachment on page 20.

7.2 Indicate the quantities of these reagents produced in the country by type and volume, e.g. anti-A typing serum 50 litres, etc.
Not produced in the country.

7.3 Indicate the serological assessment which blood donors undergo and the origin of the reagents used.
ABO, Rh, Antibody Screen - Ortho, BCA, Biotest; VDRL - BBL;
Hepatitis B - Abbott's RIA (Blood Service Centre, KL):rPHA-Green Cross, Ortho Labs.

7.4 Indicate serological assessment which recipients undergo and the origin of the reagents used.
ABO, Rh, Crossmatching tests; Antibody Screen;
Antibody Identification; Reagent Red Cells are obtained from Ortho and Blood Bank, Melbourne.

8. Use of blood and blood products

Describe briefly the regulations in effect in the country regarding the use of the principal products.

8.1 Who are the major distributors and users of blood products for diagnosis and therapy?
Distributors - Government Medical Stores
Users - Clinicians, Haemotologists, Internists (Surgeons, Anaesthetists) : Factor VIII, IX, Albumin, Globulin, Plasmanate (Albumin)

9. Blood transfusion costs

(Include costs incurred by Blood Transfusion Services and Government subsidies where appropriate)

9.1 Gross cost Probably $ 3-4 million (see Annex on page 28)

9.2 On the basis of total health program costs, indicate the proportion represented by blood transfusion programs. Not accurately known as budgeting is tied up with hospital services budget.

10. Treatment of patients suffering from haemophilia

10.1 Indicate the products used in the treatment of patients suffering from haemophilia. Approx. $ 1250 estimated costs for concentrates and Cryo per person only. Occasional patients have used up to $ M21,000/= for F VIII concentrates. Hospital costs are not taken into account.

11. Bases of co-operation

Indicate your country's requirements with respect to blood derivatives and any interest that may exist in co-operation with other countries in this area.

Country's requirement mainly -
Hepatitis B Immunoglobulin
F VIII concentrates
F IX concentrates
some Albumin 5%, 25%
Interested in cooperative efforts

12. Projects of the country

12.1 Indicate the country's projects in the area of blood donation

See photocopy of the paper entitled "The blood transfusion services in Malaysia" on pages 21-27 and Annex on page 28.

12.2 Indicate any projects the country may have, at the national or regional level, regarding industrial blood-fractionation facilities

Too expensive to establish in the near future

Lack of specialists

Insufficient amount of plasma

Therefore not feasible to establish a plant within the near future (not within the next 7-10 years)

A blood centre which is geared to recruitment of donors, donor care, component preparation, training, reagent product should be developed first.

ATTACHEMENT

7. Reagents used in immunohaematology

7.1 Indicate the type of reagents and the quantities used annually.

Blood Services Centre, K.L.

Anti A	1200 vials
Anti B	12[illegible] vials
Anti A,B	400 vials
Anti H	50 vials
Anti D	1200 vials
Anti CDE	50 vials
Anti [illegible], c	120 vials
Anti M, N, etc	80 vials
Anti Human Globulin (Broad Spectrum)	
Anti IgG, Anti Complement	2500 vials
Anti Lewis^{a}	130 vials
Anti Lewis^{b}	130 vials
Anti Jk^{a}	10 vials
Anti Jk^{b}	12 vials
Anti Kell	15 vials
Anti k	15 vials

THE BLOOD TRANSFUSION SERVICES IN MALAYSIA

by C.G. López, MBBS, DCP, FRCPA*
(Malaysian J. Pathol, August 1983, pp. 1-7)

INTRODUCTION

The special nature of Blood Transfusion Services has been very well described by Wolf[1] who states that "unlike other clinical laboratories the blood bank provides a parenteral therapeutic agent. Unlike the pharmacy's primarily *synthetic* parenterals, blood and its components resemble tissue or organ transplants. They require individual patient-donor matching. The unique aspects of transfusion practice are attributable to the complexity of the biological agent administered, the resultant sequelae, its perishability, and the vagaries of a supply that is dependent on a complex technology of collection and the good will and cooperation of physicians, patients, and the general public. It is these factors which increasingly determine the activities of the hospital blood bank and explain its evolution towards a transfusion service quite unlike its sister laboratories, and not entirely similar to the pharmacy or the organ transplant service, yet sharing with them several important similarities. At the same time, the service continues to have an important role as a diagnostic laboratory not unlike that of any other clinical laboratory. In this role, the blood service shares the same organizational and managerial problems common to all clinical laboratories and all too familiar to clinicans such as prompt and accurate reporting of results and reliability of assays".

Therefore the important considerations in the organization of a Blood Tranfusion Service are (i) the complexities of blood and its use as several vital therapeutic agents, (ii) the dangers involved and technology required in its administration, (iii) the safe, effective and economical utilization of blood, (iv) the problems associated with the need to maintain continuous supplies in the face of increasing and seasonal peak demands of a necessarily limited resource, (v) the need for co-operation and good will of people at both hospital and public levels as well as the need for public relation skills, (vi) the need for close co-operation of all blood banks in the country and co-ordinated planning in order to project future needs.

In recent years, blood component therapy has made a great impact in the more effective management of various disorders. Many of the components of blood such as fresh frozen plasma, cryoprecipitate, packed red cells and platelet concentrates, can be easily prepared in blood bank laboratories equipped with blood bank centrifuges. Many other derivatives of blood of therapeutic value can be fractionated. However this type of processing requires the use of much more sophisticated machinery. Today as many as 20 therapeutic agents can be produced from blood as distinct components and fractions.

While blood transfusion is like a miracle life saving drug, it is important to recognize that the procedure can be dangerous to patients, that every activity involved in the handling of blood from the initial donor interview to eventual blood transfusion can affect the quality, safety and efficacy of blood transfusions. As the effective and safe use of various blood components and products in a variety of clinical conditions are important considerations, a strong clinical bias is certainly necessary in the organization of transfusion services, apart from the establishment of appropriate technology, general blood bank management, and quality control systems. While certain aspects of laboratory management do resemble that of other clinical laboratories, there are aspects peculiar to blood bank laboratories e.g. problems of blood inventory, control and the proper storage, despatch and transport of blood. The grouping, cross-matching and serological procedures have also to be considered.

As the transfusion service is dependent on community support and the good-will and generosity of the public, continuing meaningful publicity programmes at national and local levels combined with well organized expert bleeding teams are essential to ensure the ready availability and supply of blood.

Because of the obvious limitation of procurement of blood, resource sharing activities have to be developed. An integrated network of blood banks having the same standards of performance throughout the country would be able to share blood resources resulting in efficient utilization of every unit of blood collected. Such a co-ordinated national system

*Director, National Blood Services Centre, General Hospital, Kuala Lumpur. (Address for reprint requests)

would also ensure that the whole country would have equal access to the full range of activities for patient care. Furthermore it would also be possible to fulfil sudden increases in demands more efficiently e.g. in the event of national or local disasters.

Against this background illustrating the complexities of running a transfusion service, we can now consider how the transfusion services in Malaysia have met these challenges. It is perhaps best to start with a short history of the early beginnings of the service.

THE ORGANISATION OF TRANSFUSION SERVICES IN MALAYSIA.

Early Beginnings

As early as 1950, the importance of blood transfusion as a life-saving procedure was recognized in Malaysia, as there are records of donors having donated to the Blood Bank, General Hospital, Kuala Lumpur in that year.

In 1955 the Blood Bank (then known as the Selangor Blood Bank) was run by a British Red Cross lady volunteer and the Bank only operated once a week on Wednesday from 5.00 pm. to 6.30 p.m. The average number of donors per week was 25 and the highest obtained was 44 donors in a week. There was apparently good co-operation from the police, army and government departments and the blood collected was said to be just sufficient to meet the demand. It was realised even then that the Blood Bank could not depend on random donors and attempts were made to purchase a mobile blood donor van. This idea was however shelved due to lack of funds. The Jaycees (Junior Chamber of Commerce) was actively involved in recruiting donors.

From 1958 onwards a medical officer appointed by the Ministry of Health was attached part time to the Blood Bank and later in the same year a supervisor was appointed to take overall charge full-time.

In 1961 the staff of the Blood Bank of the General Hospital, Kuala Lumpur comprised one medical officer, two supervisors, two assistant nurses and one attendant. In 1970 the number of blood units collected increased to 5803 and a total of 13860 cross-matchings were undertaken. In 1971 the Blood Bank moved to the present premises.

Launching of the National Blood Transfusion Services

In April 1972 the National Blood Transfusion Service was launched by the Director-General of Health Services with the National Blood Transfusion Centre set up as "an independent body sited at the Blood Services Centre, Hospital Besar, Kuala Lumpur integrating all government hospital blood banks services in the country including the serving of the Hospital Besar with proper staff and facilities under the Hospital Division of the Ministry of Health". A full time director (Haemotologist) was appointed.

Progress in the development of the National Blood Transfusion Services

By 1975 standardization was brought about throughout the country in all government hospital blood banks in various aspects of blood banking e.g. rules of work, stationery, methodology, reagents, staffing and equipment. Training courses for medical officers and laboratory technologists were conducted with WHO assistance to improve standards of serology practice in blood bank laboratories. Basic text-books were made available to consolidate the training programmes. The plastic blood bag system was introduced, replacing the old practice of collecting blood in glass bottles which carried considerable risks to both patients and donors. The plastic blood bag system enabled blood banks particularly the Blood Services Centre, Kuala Lumpur to produce blood components e.g. fresh frozen plasma, cryoprecipitate, platelet concentrates, packed red cells and washed red cells. Budgeting for running the National Blood Transfusion Services was drawn up and was estimated to be $1.9 million (excluding special expenditure items) in 1975 [2]. The compilation of national annual data on transfusion services provided essential information on progress and data for development possibilities, for public consumption, and donor recruitment exercises.

Apart from transfusion services, specialized haematology services were also provided by the Blood Services Centre to the General Hospital. This linkage of transfusion services with haematology proved to be advantageous, providing a better understanding of transfusion needs for patients and unique opportunities for medical officers and technologists for comprehensive and meaningful training in both transfusion and haematology in the same premises. It also provided a strong clinical bias to transfusion services which as pointed out earlier is an important aspect in the organization of transfusion services. The continuing function of the centre include providing transfusion services to the General Hospital, referral services for transfusion problems for the country, routine

and referral haematology services for the investigation and management of patients, and central registry for haemophilia. The investigation for Hepatitis B infection in blood donors, patients, contacts and staff is also the special responsibility related to transfusion services carried out by the Centre.

TYPE OF ORGANIZATION

The type of organization of transfusion services may differ considerably from country to country. It may be an independent organization completely divorced from hospital services, its functions being mainly collection, processing, special despatch of blood and research activities which are carried out by very large centres run by specialist haematologists while the actual hospital transfusion services and haematology services together are looked after by other specialist haematologists (as in Australia) The services could be under governmental control or under Red Cross but funded by the government (as in Australia) or under some other form of community organization. It could be pluralistic as in the United States in the sense that different groups of blood banks in the country operate under differing policies and different organizations instead of ideally operating under one type of system only. There could be many regional centres each having its own director but without the advantage of central co-ordination by a National Director (as in U.K.).

... Malaysia almost all the blood banks are attached to government hospitals i.e. the organization is fundamentally hospital based and hospital controlled There are 60 hospitals in Peninsular Malaysia and 32 hospitals in East Malaysia, 13 of which may be designated as having regional blood banks The National Blood Services Centre is itself part of the General Hospital Kuala Lumpur.

In countries with well organized transfusion services, many specialists are available to run the service at all levels i.e. at central, regional and hospital levels In Malaysia there is a paucity of specialists for transfusion and haematology services. Only 2 haematologists (Director and Deputy Director) are available. Furthermore the service is essentially hospital based and controlled. However within this setting it has been possible to provide a clinically orientated transfusion service as well as develop special fields of clinical significance i.e Haemophilia and Hepatitis B infection. The speciality of blood transfusion is not generally considered an "attractive" posting for Malaysian doctors. The development of and emphasis on the clinical aspect of blood transfusion has therefore played an important role in attracting suitable medical officers for the service, and will continue to provide a suitable training environment in all aspects of transfusion and haematology in the country for future specialists

Hollan in a recent report[3] states that the lack of experts in developing countries is one of the most important limiting factors in the development of National Blood Transfusion Services (NBTS) She states that since haematology and immunology overlap and intersect with blood transfusion, the best solution would be to train physicians (medical officers) in blood tranfusion, haematology and immunology in a combined specialists training scheme

The basic framework of the transfusion service in Malaysia resembles to some extent the Hungarian Blood Transfusion Services Excerpts from the report[4] on the latter are as follows.–

1. The Hungarian Blood Transfusion Services is governmental . . . supported by funds advanced to the Ministry of Health.
2. The service is centralized. Professional guidance and control are exercised by a Centre for Haematology and Blood Transfusion
3. All other blood transfusion centres in the country operate within hospitals . . . . . The Central Institution of the National Blood Transfusion Service (N.B.T.S.) functions directly under the Ministry of Health, while the regional, country and other blood transfusion centres are supervised by the Centre.

In summary, the Hungarian Blood Transfusion Service is said to have greatly benefited from the fact that the Centre directs and controls the national network of blood banks and that besides the production of blood and blood components, it also treats haematological patients directly and works in unison in the areas of blood transfusion, haematology and immunology.

The above system is cited as reasons for a highly developed blood transfusion service in Hungary.

Another reason for rapid growth was attributed to the close organizational and scientific co-operation between the three disciplines; blood transfusion, haematology and immunology. "The centre is also actively involved in the treatment of haematological patients . . . New scientific achievements, new or improved methods are passed on imme-

diately to the 65 regional centres. The intimate connection with clinical practice, among others, attracts well trained physicians (doctors) and other science graduates to work and stay in the service . . ."

POLICY AND AIMS

Because of world wide problems and hazards of transfusion services, the World Health Organization at its 28 World Health Assembly in Geneva in May 1975 urged all member states

(a) to promote the development of national blood services based on voluntary non-remunerated donation of blood,
(b) to enact effective legislation governing the operation of blood services and to take other actions necessary to protect and promote the health of blood donors and of recipients of blood and blood products

The early history of blood transfusion practice in this country geared the services towards a voluntary non remunerative system, and most blood banks attempted to recruit donors based on these principles. Furthermore a national policy for a non remunerated system for donor recruitment was formalized in 1979, when the first National Seminar for Transfusion Services was held. At that time the private sector was also represented to discuss the problems of transfusion services. It was officially established that the Natonal Transfusion Services incooperating all blood banks in the country would be run on a voluntary non remunerative system. Some of the aims and goals laid down at this seminar were as follows.

1. To encourage, foster and support efforts to form a totally voluntary non-remunerative blood donation system,
2. To achieve a target of 10% of adult urban or 2% of the general population in donor recruitment in all states in Malaysia. Under this system mobile and group donations were to be increased.
3. Greater centralization of donor recruitment was to be brought about to prevent unnecessary competition for donors, particularly in the main cities.
4. Replacement donors were to be gradually abolished. Mobile and group donations were to be increased.
5. Component therapy was to be increased and whole blood transfused reduced progressively to not more than 20%.

FUTURE DEVELOPMENT

While at the present time, there is no unified centrally managed truely "National Blood Transfusion Services", the basic frame work of this services has already been established such as standardization of methodology and various aspects of laboratory management. The Blood Services Centre also functions as a referral centre for transfusion, haematology problems, haemophilia and hepatitis and provides the strong clinical bias that is necessary in modern transfusion practice. Organization of transfusion services based on a centre carrying out combined activities of blood transfusion with haematology has been found to be very successful and is recommended by Hollan[3] for transfusion services in developing countries. Donor recruitment policy has been established based on the 1975 WHO Assembly and on the Code of Ethics of the International Society of Blood Transfusion and certain goals and aims have been outlined. Some of these goals have been met. The number of blood units donated in the whole country has increased (Table 1). In Kuala Lumpur the amount of blood collected at the Blood Services Centre has increased to 22,866 units in 1983. More than 65% are from non replacement civilian donors (Table 2). The number of blood units collected in the Wilayah/Petaling Jaya area in 1983 amounts to more than 35,500 (Table 3). 3.2% of the population in this area appear to be donors (Table 4). Almost 50-60% of the blood collected at the Blood Services Centre are separated into components. In all other blood banks it is mostly whole blood that is used.

As more haematologists become available, considerable improvements to both transfusion and haematology services can be expected together with better co-ordination of services on a national scale. Trained medical officers and specialist haematologists would act as key personnel establishing better communication between the central and peripheral counterparts in all aspects. e.g. professional, supplies, referrals and administration. It would also be possible to increase the production of components and bring about more effective utilization of blood by promoting component therapy rather than whole blood at peripheral hospitals. While the recruitment of blood donors is an important aspect of the transfusion services, the proper utilization of blood in our hospitals is equally if not even more imporant.

Because the amount of blood collected and the amount of blood products that can be made available is necessarily limited by the number of people donating blood and presence of processing facilities, blood and blood

products should be regarded as the country's very own precious resource for vital therapeutic materials. It is important therefore to assess basic and future needs.

The basic blood requirements for the centre may be estimated from the number of acute hospital beds. It is said that to meet the requirements of 1000 emergency hospital beds, a panel of about 7000 donors is required.[5] As there are 26,816 government hospital beds in both Peninsular and East Malaysia at least 187,712 units of blood would be required. It is also said that the need for blood can be met if about 2% of the population are regular donors. However with the development of open heart surgery, renal dialysis, and other procedures using transfusion, more blood would be required. As the population of Malaysia is 13.1 million the requirements for blood would be in the region of 262,000 units if no specialised units have been developed. The quality and adequacy of transfusion services can also be guaged from the availability of blood products for haemophilia. According to world statistics it can be assumed that at least 50 haemophilia cases per million population can be expected. Each patient would require at least 20,000 units of Factor VIII every year. In Malaysia it is estimated at least 13 million units of Factor VIII would be required for the management of haemophilia. Therefore more than 130,000 units of blood would need to be processed for cryoprecipitate, if 100 units of Factor VIII can be extracted from each unit of blood. However as the sole use of cryoprecipitate has several serious disadvantages, lyophilized concentrates would have to be produced requiring large amounts of good quality source plasma. If ideally 5% of the population donate blood it would be possible to recover 4 – 10 thousand litres of plasma from which 200 units of Factor VIII (intermediate potency, average technique) per litre could be extracted and processed in a fractionation plant, depending on the quality of source plasma, among other limiting factors affecting the Factor VIII concentration of the final product[6]. From another viewpoint each patient, utilizing 20,000 units of Factor VIII per year, would require the processing of 100 litres of plasma to produce intermediate potency concentrate.[7]

The collection of blood for the country as a whole needs to be greatly increased and component therapy promoted. As the situation in the Kuala Lumpur area is promising, a similar pattern of greater collection and more effective utilization of blood can be expected in other blood banks.

New blood banks are being established in the private sector. This would result in fragmentation of blood banking services, differing standards among the different blood banks and competition for blood donors. At the same time total effective plasma collection and utilization would be less than what can normally be expected from a centralized service. Furthermore the particular dangers associated with blood bank technology and transfusion of blood carry with it sepcial responsibilities. Constant availability of control and reagent cells and antisera are also necessary, the use of which in small blood banks may prove very expensive and impractical.

As the number of specialists in the service increase, strengthening of the existing framework of organization can be expected. A coordinated national network of blood banking and haematology services geared to serving hospitals and community can promote development of efficient, economic and effective utilization of blood and blood products and eventually self-sufficiency.

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TABLE 1

UNITS OF BLOOD COLLECTED IN 1982 AND 1983 IN MALAYSIA.

State	1982	1983
Perlis	1,850	1,685
Kedah	7,493	7,474
Pulau Pinang	7,829	7,754
Perak	11,183	11,191
Selangor	5,174	5,036
Negri Sembilan	4,682	5,164
Melaka	4,226	4,264
Johor	11,416	11,756
Pahang	4,487	4,799
Terengganu	1,981	2,180
Kelantan	6,457	6,830
Blood Services Centre, Kuala Lumpur	21,727	22,866
Peninsular Malaysia	88,505	90,999
Sabah	13,780	15,158
Sarawak	12,626	12,793
Total for Government Hospital Blood Banks	114,911	118,950
Blood units collected from other hospitals in Kuala Lumpur		
University Hospital	9,672	9,889
Chinese Maternity Hospital	280	201
Assunta Hospital	2,682	2,470
Lady Templer Hospital	324	203
	12,958	12,700
Total collection from Peninsular and East Malaysia	127,869	131,650

Ratio of Blood Donors to Population = 1.0 : 100

TABLE 2

UNITS OF BLOOD COLLECTED ACCORDING TO CATEGORY OF DONORS

	Year				
Category	1978	1979	1980	1981	1982
Civilian	10,294	11,699	13,473	14,535	14,586 (67.14%)
Army	888	1,012	1,778	1,429	1,702 (7.83%)
Police	4,113	3,122	2,330	1,501	1,567 (7.21%)
Replacement	1,013	1,888	2,715	3,004	3,872 (17.82%)
Total	16,313	17,721	20,296	20,469	21,727

TABLE 3

BLOOD COLLECTION IN WILAYAH (Kuala Lumpur City) AND PETALING JAYA

		Blood Units collected in 1974, 1982, 1983				
Hospitals		1974	1982		1983	
Blood Services Centre, General Hospital, Kuala Lupmpr.		11,533		21,727		22,866
Other Hospitals in and around Kuala Lumpur	University Hospital	6,946	9,672		9,889	
	Assunta Hosptial	•	2,682		2,407	
	Chinese Maternity	•	280		201	
	Lady Templer	•	324		203	-
Total of 4 Hospitals		•		12,959		12,700
TOTAL COLLECTION				34,686		35,566

• Not known.

TABLE 4

RATIO OF BLOOD DONORS TO POPULATION IN THE WILAYAH/PETALING JAYA AREA

Area	Population (1980 Census Report)	Total Donations in 1983
Wilayah (Kuala Lumpur City)	919,610	23,270
Petaling Jaya	207,805	12,296
Total	1,127,415	35,566

Ratio of blood donors to population = 3.2 :100

Annex

ESTIMATED OPERATING COST OF NATIONAL BLOOD TRANSFUSION SERVICE 1975 - 1976

SUMMARY OF COST O. C. S. E.

Recurrent Expenditure	Stationery & Printing (includes printing of pamphlets, etc.	Training Projects, Books & Journals	Special Project Basic Equipment (local manufacture)	Transport Vehicle All purpose van	Blood Donor Badges	Travelling & Mileage (Blood collection supervision of laboratories)	Telegrams Air Freight within and outside country	O. Above $500/-	C. S. Below $500/-	E. TOTAL FOR O.C.S.E.
$	$	$	$	$	$	$	$	$	$	$
[illegible]	22 200.00	36 150.00	2 760.00	-	38.910.00	4 700.00	500.00	233 000.00	14 404.00	247 404.00
	2 500.00	-	4 050.00	-	3 600.00	500.00	-	24 500.00	5 440.00	29 940.00
114 [illegible]	7 400.00	-	8 060.00	16 000.00	8 030.00	2 000.00	-	123 600.00	10 875.00	134 475.00
101 [illegible]	8 000.00	-	8 060.00	16 000.00(Muar)	26 000.00	2 000.00	-	83 525.00	11 525.00	96 055.00
33 [illegible]	6 000.00	-	2 760.00	-	3 500.00	500.00	-	3 900.00	1 630.00	5 300.00
33 [illegible]	4 700.00	-	2 760.00	-	8 850.00	500.00	-	18 250.00	2 945.00	21 195.00
33 [illegible]	5 500.00	-	2 760.00	-	10 340.00	500.00	-	5 365.00	15 450.00	20 815.00
33 [illegible]	2 500.00	-	2 760.00	-	25 000.00	1 000.00	-	36 200.00	5 470.00	41 670.00
28 244.00	2 500.00	-	1 760.00	-	8 850.00	300.00	-	7 400.00	565.00	7 965.00
28 244.00	2 500.00	-	2 260.00	16 000.00	9 995.00	500.00	-	21 100.00	1 325.00	22 425.00
10 911.00	2 000.00	-	1 760.00	-	4 520.00	200.00	-	7 790.00	390.00	7 550.00
10 911.00	1 000.00	-	1 760.00	16 000.00	8 640.00	500.00	-	17 850.00	1 205.00	19 055.00
33 [illegible]	7 400.00	-	1 760.00	16 000.00	-	-	-	74 650.00	6 660.00	19 055.00
28 244.00	7 400.00	-	1 760.00	16 000.00	-	-	-	36 700.00	2 865.00	39 565.00
93 [illegible]	82 400.00	36 150.00	44 650.00	96 000.00	156 235.00	13 200.00	500.00	694 235.00	182 769.00	776 144.00

[illegible]

SINGAPORE

As for all other countries visited, I had written to both the Ministry of Health and the Blood Transfusion Service to arrange appointments for my interviews. Despite my own personal efforts and those of the UNDP representative in Kuala Lumpur, however, it was not possible to arrange a meeting with Dr. Kwa, the Director of Medical Services or any of his senior officers. I did have an appointment with Dr. Ong, the Director of the Singapore National Blood Transfusion Service and was told that as the Service is part of the Ministry of Health, Dr. Ong would be able to present her own as well as the Ministry's views.

The Singapore Blood Transfusion Service is located in the Singapore General Hospital (SGH) where they have a donor bleeding centre and also occupy space in the Haematology Department of a recently completed laboratory services wing. Blood is collected at the Central Blood Bank by mobile teams and since recently by the Red Cross Society at a separate fixed location.

Neither the BTS nor the Ministry had completed the questionnaire that I had sent out in early April. I was told that a decision had not yet been taken at Ministerial level whether to participate in the UNDP programme for the production of biologicals and that consequently they were not currently in a position to provide answers to all the questions I had posed. It was agreed that if the Ministry's decision to supply the information was favourable the questionnaire would be completed and forwarded to UNIDO's head office in Vienna. If not considered confidential, a copy would also be sent to me to be included as an addendum to this report.

Singapore is a small country with a population of approximately 2.5 million. Last year the Service collected some 60,000 donations. Besides supplying the needs of SGH, the BTS* also services five other large Government hospitals as well as the needs of private hospitals.

Donors currently represent 2.3 percent of the population (23 per 1000) which Dr. Ong believes is a little on the low side. They occasionally have difficulty in meeting demands for cryoprecipitate and she would be more comfortable with a donor rate of 40 per 1000. Singaporeans are not conditioned to be blood donors and there is a significant apathy and ignorance that needs to be overcome.

All blood collected in Singapore is from voluntary donors. As mentioned above, the Red Cross Society has recently also set up a blood collection programme but this is still in its infancy; less than 5000 units were collected in 1984. All distribution of blood is, however, handled through the National BTS. Although donors are not paid, a scheme of medical privileges is available to regular donors and their nominees. These privileges include reductions in hospital ward charges, exemption from certain hospital fees and outpatient benefits. The time limit for such benefits lengthens in relation to the number of donations given. For example, after 50 donations, a donor is entitled to ten years of medical benefits.

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* Blood Transfusion Service

Of the 60,000 donations collected in 1984, 50 percent were issued as whole blood and 50 percent fractionated into components. Some 9000-10,000 donations were processed to cryoprecipitate which was the main form of treatment used for Singapores 200 haemophiliacs (of this total, 150 have Haemophilia A, the remainder suffering from Von Willebrand's disease, Haemophilia B and other less common bleeding disorders). Approximately five percent of Haemophilia A patients have developed inhibitors, all of which seem to be of the low level type. A small stock of lyophilised commercial AHF* is held for emergency use but it is very expensive and its use is discouraged. Dr. Ong is also thinking about the production of lyophilised cryoprecipitate which can be stored at 2°-8°C thus reducing the need for deep-freeze units and simplifying transportation to other hospitals and end-users.

Approximately 10,000 units of fresh frozen plasma are prepared annually. The usage varies due to changes in treatment fashions but currently the main indications are disseminated intravascular coagulation, assorted bleeding states of uncertain or mixed aetiology and as replacement in patients undergoing therapeutic plasmapheresis.

Singapore is currently sending some 3000 litres (equivalent to 15,000 donations) of plasma annually to Australia for fractionation into Albumin. Dr. Ong commented that this programme is very expensive and that they propose to look at alternative local options, eg the acquisition of a Sephamatic unit.

The remaining plasma not accounted for above, is used as a plasma volume expander in preference to Albumin (too expensive) or to artificial plasma volume expanders (Dextrans, collagen, etc). In fact, large volumes of crystalloids are preferred to the latter. If Albumin could be made available more readily and cheaply, it would be used in preference to other colloids.

Blood and blood products are not sold. A nominal processing fee is charged for product issued by the Blood Bank but as 80 percent of these go to patients who are highly subsidised in one way or another, the Service may only recover 10-15 percent of the nominal charge that it makes. Both the BTS and Red Cross have their blood collection budgets allocated by the Ministry of Health.

Normal Immunoglobulin is not widely used but there is a need for some hyperimmune immunoglobulins, for example, HBIg as part of a Government programme to reduce the HBsAg carrier rate by passive/active immunisation of infants born to carrier mothers.

Several years ago, some two-thirds of all blood was collected by mobile teams, the pattern has now changed and last year a little over 50 percent of blood was taken at the Central Blood Bank. The establishment of regional centres for blood collection is currently under consideration.

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* Anti-hemophilic factor.

The impression gained from my brief visit was that Singapore is more a developed than a developing country. They are anxious to introduce "high technology" wherever possible, including the field of blood and blood products. The fact that they are independently looking at alternatives for the production of Albumin and their difficulty in deciding whether to contribute information for a potential regional collaborative programme suggests to me that they may well be considering a unilateral foray into this field.

INDONESIA

In Jakarta, I called on Dr. Masri Rustam, Chief of Blood Transfusion Division of the Indonesian Red Cross Society and on Dr. H. Mohamad Isa, Director-General, Medical Care, Ministry of Health.

In Indonesia, the Red Cross Society is by law the only organisation empowered to collect blood for the needs of the country. This is done on an entirely voluntary basis although the situation as it currently stands was only reached some four years ago. Approximately 400,000 donations are collected annually by some 110 individual Red Cross chapters or branches. In all but a few cases, these are independent of and not attached to the local hospital services. The 400,000 donations referred to above represent the contributions of some 200,000-250,000 individual donors. Dr. Rustam estimates the donation rate at two percent (20 per 1000 population) but according to my calculations the ratio is much lower (0.2 percent). He admits that plasma intake for a successful fractionation programme will require a significant increase in donor numbers and/or a better utilisation of current resources. A great deal of potential plasma is currently being wasted because of the use of single donor packs. The reason for the latter is that the Red Cross Society must provide the funds for these consumables and they presently cannot afford to buy more than a minimum quantity of multiple packs.

Although donors are not remunerated and the sale of blood or blood products is prohibited by law, the Red Cross charges the patient a processing fee for the delivery of blood or blood products such as packed cells and fresh frozen plasma. This may range up to $US12.00 per product with a mean figure of $5.00-$6.00. Monies raised in this way must cover the operating costs of the service although over the past four years the Government has paid the Society a subsidy for the purchase of capital equipment and to cover the costs of its various training programmes. Unfortunately, these funds have not kept pace with the rate of inflation and the falling value of the rupiah.

While the demands for whole blood can be met, this is not the case for fractionated blood products. Albumin is chronically in short supply and the price of the imported product is prohibitive. Thus, 25 grams of Albumin imported from the US cost $US150.00. Because they believe there is no substitute for the use of Albumin in the management of open cardiac surgery patients, they currently have arrangements with the Netherlands Red Cross whereby the latter supplies them with 600 units of Albumin annually at a much more favourable price for the management of these cases. Given the choice, Dr. Rustam and the local clinicians would prefer to use human Albumin over other plasma volume expanders in the management of shock and Dr. Rustam has proposed the purchase of a chromatography unit from Pharmacia for the production of this fraction to the Ministry of Health. He believes that Jakarta, Surabaya, Bandung and some 10-12 other medium sized blood banks could between them contribute some 200 litres of plasma per week which would be required to operate such a plant economically.

There seems to be very little severe haemophilia recognised in Indonesia and consequently they do not foresee the need to upgrade or to increase their Factor VIII production. The few diagnosed patients are managed adequately with cryoprecipitate of which Dr. Rustam is required to produce only some 2000-3000 units per annum.

Their current requirements for Normal Immunoglobulin are very small and the specific immunoglobulins are rarely called for. There currently is no Government programme to reduce the incidence of Hepatitis B carriers by passive/active immunisation and Dr. Rustam believes there is unlikely to be one until the current price of the Hepatitis B vaccine comes down considerably.

Because of the need to contain overall operating costs which must be recovered from end-users, Dr. Rustam has been reluctant to introduce unnecessary tests into the BTS. Thus, it is only in the last 12 months that they have routinely started testing all donations for HBsAg and find that they have a sero-positivity rate of 4-5 percent. This is of immediate concern because it means that they must increase their donor rolls to compensate for the five percent of blood collected that will now be rejected for transfusion. There is, of course, a tremendous potential to increase donor numbers overall in a population of 162 million but it must be remembered that 78 percent are rural dwellers and the economics of education campaigns, the setting up of new collection centres, the purchase of more mobile units and the increase in transportation costs must all be calculated and weighed against the possible advantages, eg greater self-sufficiency in lifesaving products and possible savings in foreign exchange.

One of Dr. Rustam's concerns about the pooling of plasma from different countries if a fractionation plant were to be established as a cooperative effort in the ASEAN region, relates to the potential spread of AIDS through the blood supply. Three HTLV-III antibody positive individuals have recently been identified among Singapore's homosexual population (all are homosexual prostitutes). Dr. Rustam is worried that such a plant may facilitate the spread of this infection and others. While appreciating his concern, I believe it is possible to build safeguards into a plant and the processes used in it that will minimise such risks.

In summary, I believe that Dr. Rustam would welcome greater access to fractionated blood products, especially Albumin, but feels that Indonesia with a large population and a fairly centralised blood collection system should be able to provide enough plasma to feed its own stand alone fractionation plant, eg a chromatography unit. He put this proposal to the Ministry some two years ago and is hoping for their support.

Dr. Isa's thoughts complemented those of Dr. Rustam as I had expected. The Ministry sees the need for fractionated blood products to be made available more freely and at a more reasonable price but strongly favours the establishment of an Indonesian based project at least in the first place. Dr. Isa believes that the tremendous

logistic problems that the Government has in supplying its citizens strung out over a distance of 6000 miles and living on numerous islands could be vastly improved if more stable blood products were available. He believes that it is now up to the Red Cross Society to come up with a firm proposal on what type of fractionation unit should be set up, where it should be located, its capacity, what products it should produce, etc. The Government will give such a plan its consideration and if it recommends the go ahead will then investigate ways of financing such a development, eg from its own funds, through the World Bank, by means of a low interest loan from Japan, etc. Dr. Isa did not rule out the possibility that Indonesia would collaborate with other ASEAN countries in the establishment and running of a regional fractionation centre but felt that Indonesia's needs were sufficiently large and urgent for it to plan its own facility and suggested that consideration might be given to making some of the byproducts not immediately required by Indonesia available to others. How this could be done would have to be explored as it is not currently legal to sell or to export blood fractions from Indonesia. I pointed out that it might be possible to charge a processing fee rather than to sell the actual plasma product derived from a voluntary blood donation. Dr. Isa left me in no doubt that Indonesia sees its primary responsibility as providing blood fractions for the domestic market and that any ASEAN collaborative exercise in this area would have to take second place. He saw no problem in identifying suitable scientists and technical people for the necessary training abroad when the time comes.

SUPPLY OF BLOOD & BLOOD PRODUCTS QUESTIONNAIRE

1. Name of country Indonesia

2. Population

   (a) Total 162.000.000

   (b) % living in major cities & regional centres (numbers ≥50,000/centre) 22 %

   (c) % rural dwellers 78 %

3. Describe briefly existing blood transfusion services

   (a) Centralised blood banks
   Executed by Indonesian Red Cross according to Governmental Regulation.

   (b) Hospital-based blood banks
   As exception: Army Hospital & Oil Company Hospital.

   (c) Mobile blood collection services
   Yes, we have ± 50 Vehicles.

   (d) Regional distribution networks

   Attached to Red Cross Chapters in the region.
   Altogether there are 101 Chapters involved.

   (e) Other

4. Blood donation

   4.1 Total number of donors 400.000

   4.2 Classification of donors

   4.2.1 Number of voluntary unpaid donors 320.000
   4.2.2 Number of voluntary paid donors
   4.2.3 Number of professional donors
   4.2.4 Others
   Number of replacement donors 80.000

4.3 How many donations are collected annually and used as:

(a) whole blood 300.000

(b) red cell concentrates 100.000

(c) plasma (give volume in litres). 2.500 litres.

If plasma is obtained other than as a by-product of red cell concentrates e.g. by plasmaphereses, indicate the additional volume collected annually (in litres).

4.4 Which of the following organisations are responsible for blood collection in your country? Indicate percentage that each contributes to the overali collection.

4.4.1 Nationally funded an controlled blood banks % 0

4.4.2 Blood banks belonging to other organisations % 95
e.g. Red Cross

4.4.3 Commercial blood banks % 0

4.4.4 Others (Army Hospital & Oil Company Hospital) % 0

4.5 List the biomedical tests performed on donors (please tick)

4.5.1 Chemical

Haemoglobin estimation	X
Serum protein level	...
Serum iron	...
Serum bilirubin	...
Other (specify)	...

4.5.2 Biological

Syphilis	X
Hepatitis B	X Some of BTS --- In 1985
Malaria	1986 will be started at all BTS.
AIDS	...

4.6 Transmissible disease among donors (state their frequency):

4.6.1 Hepatitis B	4,5%
4.6.2 Malaria	no report
4.6.3 Other parasitoses (specify)	-
4.6.4 AIDS	-
4.6.5 Others (specify)	-

5. Production of non-stable (cellular) derivatives

5.1 Indicate for the following products the quantities collected/prepared and used:

	Collected/Prepared	Used
5.1.1 Whole blood	300.000	
5.1.2 Red cell concentrate	100.000	almost all of them are used.
5.1.3 Frozen fresh plasma	10.000	
5.1.4 Dry plasma	-	
5.1.5 Platelet concentrate	12.000	
5.1.6 White cell concentrate	600	
5.1.7 Others		

5.2 Indicate the imported and exported quantities of the above mentioned products and the origin of the imports.

6. Production of stable derivatives

6.1 Indicate for the following products the quantities produced and used: (all hospitals).

		Proposed	Used(approx)
6.1.1	Albumin (including PPF or SPPS)		
6.1.2	Factor VIII(Cryoprecipitate)	2.500	mostly used
6.1.3	Factor IX		
6.1.4	Immunoglobulins (a) Normal (b) Spec. ic		
6.1.5	Other Fibrinogen		

6.2 Indicate the imported and exported quantities of the abovementioned products and the origin of the imports.
Albumin are imported from CLB for openheart surgery 600 btl/year & commercially from USA (Cutter ?);quantity: no information.

6.3 Quantity of plasma collected annually.
The capacity : 10.000 - 15.000 1, but mostly wasted.

6.4 Quantity of plasma fractionated annually and by whom.
500 1 fractionated by CSL.

Production of stable derivatives.

a. At present we are trying to collect plasma as much as we can, and sent them to CSL to be fractionated into Albumin, Fibrinogen & Immunoglobulin. Originated from 500 1 of plasma we obtain 460 btls Albumin, 70 btls Fibrinogen and some Immunoglobulin which most of those products are used.

b. 600 bottles of Albumin (200 ml) are imported from The Netherlands and all of them are used.

c. Different stable products are also imported commercially from USA (Cutter). The quantity is not known for us.

7. Reagents used in immunohaematology

7.1 Indicate the type of reagents and the quantities used annually.
ABO grouping reagents 100 l.

7.2 Indicate the quantities of these reagents produced in the country by type and volume, e.g. anti-A typing serum 50 litres, etc.
ABO grouping reagents 100 l.

7.3 Indicate the serological assessment which blood donors undergo and the origin of the reagents used.
ABO grouping by own product reagents.
Rh typing by Ortho product reagents.

7.4 Indicate serological assessment which recipients undergo and the origin of the reagents used.
ABO grouping by own product reagents
Rh typing by Ortho product reagents.

8. Use of blood and blood products

Describe briefly the regulations in effect in the country regarding the use of the principal products.

8.1 Who are the major distributors and users of blood products for diagnosis and therapy?
The major distributor is BTS of Red Cross Society.
The major users of blood products for diagnosis are Red Cross BTS, for therapy are Hospital.

9. Blood transfusion costs

(Include costs incurred by Blood Transfusion Services and Government subsidies where appropriate)

9.1 Gross cost Rp. 2.400.000.000,-

9.2 On the basis of total health program costs, indicate the proportion represented by blood transfusion programs. 6%.
(Not include health program cost at private sector)

10. Treatment of patients suffering from haemophilia

10.1 Indicate the products used in the treatment of patients suffering from haemophilia.
No report

10.2 Indicate the annual cost of the treatment of patients suffering from haemophilia.
No report

11. Bases of co-operation

Indicate your country's requirements with respect to blood derivatives and any interest that may exist in co-operation with other countries in this area.

Since last 2 year we had cooperated with CSL as a try out period.
For long time cooperation we still approval both National Board of Indonesian Red Cross Society and Ministry of Health

12. Projects of the country

12.1 Indicate the country's projects in the area of blood donation

Increasing by 10% of donation/year

12.2 Indicate any projects the country may have, at the national or regional level, regarding industrial blood-fractionation facilities

Medium range program :

Fractionation plant with capacity 250 litres per week

(Chromatographic method).

THAILAND

At the National Blood Centre* of the Thai Red Cross Society in Bangkok I had discussions with -

Dr. Srivilai Tanprasert, Acting Director

Dr. Sawong, Head of Fractionation

Dr. Rachanee O'Charoen, Chief, Immunohaematology Reference Laboratory

Thailand has a population of 50.5 million inhabitants of whom 85 percent live in rural areas, ten percent in Bangkok and the remaining five percent in other cities and towns. The Red Cross Society is charged with the responsibility of blood collection which in 90 percent of cases is obtained from voluntary unpaid donors. The remaining ten percent represents replacement donations collected by some hospitals from patients' relatives and a small number of professional donors in the private system. A total number of donors on the Red Cross rolls is 600,000.

In 1984, the Red Cross collected in excess of 500,000 donations throughout Thailand; 40 percent of the total being collected in metropolitan Bangkok. Thus, while the overall collection rate nationwide is of the order of one percent, the corresponding figure for Bangkok is four percent. Donors give blood from one to four times per year.

Whole blood is still the major product issued by the Society for clinical use. Only 14 percent of donations taken in 1984 were processed to red cell concentrates and other fractions. The reasons for this are partly habit and partly economical. The availability and advantages of the use of fractions are still not widely appreciated by the medical community and an educational campaign needs to be mounted to get this message across. Because of financial constraints, they are also limited in the number of double packs that they can use. Indeed, all blood not destined for component therapy is still collected into glass bottles because of the latter's lower cost.

No charge is made to patients or to hospitals for blood or blood products provided by the Red Cross. They do not even levy a processing fee although the introduction of one is under consideration. The sale of therapeutic blood products is prohibited by law but there are some exceptions, eg the importation of small quantities of Albumin mainly for use on private patients. The latter tends to be self-limiting as a bottle of 25 grams of Albumin currently costs 2000 bahts.

All donors are screened for the Hepatitis B surface antigen, the incidence of sero-positivity being ten percent. Such donations are not used clinically but recently the plasma has been separated and forwarded to the Dutch Red Cross in Amsterdam where it is used as a source material for their Hepatitis B vaccine. Donors are also

* See Appendix 4

excluded if they give a recent history of clinical malaria. Beside the usual products prepared by a major transfusion service, they also make fresh dried plasma (as single units) which is used mainly in haemophilia home care programmes.

Dr. Sawong has studied plasma fractionation technology in Montpelier, France and Berne, Switzerland and they have recently installed equipment to enable them to carry out small scale Cohn cold ethanol plasma fractionation in Bangkok. The plant is still in its commissioning phase but when it is operational they hope to process 60 litres of plasma every fortnight. Initially they intend to produce Albumin and specific immunoglobulins, viz Hepatitis B Immunoglobulin and Rabies Immunoglobulin. They are seeking further transfer of fractionation technology and would like to send somebody to CSL* to study the quality assurance aspects.

Haemophilia is currently being managed with wet frozen cryoprecipitate of which they produce some 1500 units per month (18,000 units annually) and there does not seem to be any great demand for a more concentrated product to manage problems such as inhibitors, major surgery, etc.

The National Transfusion Centre, by its example, has already demonstrated that it recognises the need for fractionated blood products in Thailand. The fractionation facility has been well thought out and equipped with some of the equipment being manufactured locally to the Centre's specifications at considerable cost savings. The Thai Red Cross Society is to be congratulated on taking this very worthwhile initiative.

In Bangkok, I also visited the Ministry of Public Health and Siriraj Hospital, the major teaching hospital of Mahidol University and the largest hospital in the country. Dr. Hatai Chitanondh, Acting Director-General of the Department of Medical Services in the Ministry believes that the primary responsibility for the supply of blood and blood products rests with the Thai Red Cross Society. Although Dr. Hatai has only been in his present post since May, his staff had done an excellent job in preparing the data for the questionnaire that I had previously sent out (Appendix 5). This clearly shows that for the 12 major centres surveyed, although the Red Cross is the major supplier of whole blood and red cell concentrates, significant quantities of some fractions are produced locally, eg Siriraj used some 30,000 units of whole blood in 1984 of which only 7477 were supplied by the Red Cross; the remainder coming from volunteer donors bled at the hospital, from replacement donors (usually patients' relatives) and from a small number of professional donors that they still use.

Even accounting for the other sources of blood collected in the country, the total of some 700,000 donations per annum is still well short of the WHO recommended minimum that two percent of the population should be regular blood donors. In Thailand's case, this

* Commonwealth Serum Laboratories

target would amount to just over 1 million donations per annum and clinicians that I spoke to voiced the view that even this would be too low given the normal requirements for blood and blood products to which must be added Thailand's very heavy transfusion burden due to the high incidence of thalassemia - it is estimated that there are some 500,000 individuals with the latter disorder in the country many of whom require regular transfusion with red cells.

Dr. Hatai is supportive of the efforts being made by the Thai Red Cross Society to establish fractionation on a small scale in Bangkok and would be prepared to consider a request for Government assistance with this project if the Society believes that such Government aid is required. He is anxious to see the number of active donors in Thailand increase but again feels that the correct vehicle for such a move is the Red Cross through its donor recruitment programme. If funds are needed for educational and promotional campaigns, such requests would also get favourable departmental attention. Thailand would not be opposed to the establishment of a regional fractionation facility for the South-East Asian area and would consider the question of support if asked. They would not see such a plant taking the place of a local industry but rather that it might be complementary with Thailand taking some product from it and in turn possibly contributing others. Dr. Hatai pointed out that the Medical Services Department did not have responsibility for all hospitals in the country. In fact, some of the major ones such as Siriraj (2171 beds) and the Armed Forces hospitals are under separate control. Any policy relating to the uniform supply of blood products throughout the country would therefore have to be discussed with various Government departments and university administrations before it can be formulated and put into effect.

At Siriraj Hospital, I had discussions with the Director and staff of the hospital's blood bank. They have a continual problem to obtain enough blood to meet the legitimate needs of their surgical and medical patients. As can be seen from the statistical summary supplied for the last five years (Appendix 6), their use of components is steadily increasing and currently about one-third of all blood collected is being fractionated. The problems of cost of plastic packs and reluctance by clinicians to use components when they are offered is suffered here in common with many other places.

Albumin usage at the hospital in 1984 was just short of 153 litres and this was certainly a minimum amount because the pharmacy just could not afford to purchase any more. True need to cover such legitimate indications as open heart surgery and patients with liver and renal diseases is probably three to four times this amount. When carrying out therapeutic plasmapheresis they never replace the volume loss with Albumin-containing solutions.

The hospital, a recognised haemophilia treatment centre, is currently caring for 118 patients with Haemophilia A for whom they prepared some 5300 units of cryoprecipitate in 1984 with an average VIII C content of 120 IU. None of their patients is currently on

a home care programme because of the difficulty of storing wet frozen cryoprecipitate. The estimated cost of preparing a bag of cryoprecipitate at both Siriraj and Chulalongkorn Hospitals is 100 bahts (equivalent to approximately $US4.00).

Besides better access to Albumin and Factor VIII, there is a need for Factor IX concentrate to manage Haemophilia B and they would also welcome supplies of certain specific immunoglobulins, particularly Hepatitis B, Varicella Zoster, Rabies and Tetanus. The establishment of a national or regional fractionation centre would be warmly welcomed. While appreciative of the present efforts of the Red Cross Society in this regard, they believe that the present capacity which can only handle 60 litre batches is too small to be of practical value to the country as a whole.

SUPPLY OF BLOOD & BLOOD PRODUCTS QUESTIONNAIRE

1. Name of country Thailand

2. Population

   (a) Total 50.5 millions

   (b) % living in major cities & regional centres (numbers ≥50,000/centre)

   (c) % rural dwellers

3. Describe briefly existing blood transfusion services

   (a) Centralised blood banks
   National Blood Centre, Thai Red Cross Society

   (b) Hospital-based blood banks
   mostly hospitals in Bangkok and provincial hospitals having their own blood banks.

   (c) Mobile blood collection services
   performed by National Blood Centre, Thai Red Cross Society

   (d) Regional distribution networks
   Regional branches of National Blood Centre are operated by the Chairman of the Red Cross of the Provincial Chapters.
   Altogether there are 101 Chapters involved.

   (e) Other

4. Blood donation at the National Blood Centre & their branches

   4.1 Total number of donors 600,000

   4.2 Classification of donors

4.2.1 Number of voluntary unpaid donors	90%
4.2.2 Number of voluntary paid donors	-
4.2.3 Number of professional donors	10%
4.2.4 Others	-

4.3 How many donations are collected annually and used as: every 3 months

(a) whole blood 86 %

(b) red cell concentrates 14 %

(c) plasma (give volume in litres). 500 litres.

If plasma is obtained other than as a by-product of red cell concentrates e.g. by plasmaphereses, indicate the additional volume collected annually (in litres).

4.4 Which of the following organisations are responsible for blood collection in your country? Indicate percentage that each contributes to the overall collection.

4.4.1 Nationally funded an controlled blood banks %10

4.4.2 Blood banks belonging to other organisations %90
e.g. Red Cross

4.4.3 Commercial blood banks % -

4.4.4 Others % -

4.5 List the biomedical tests performed on donors (please tick)

4.5.1 Chemical

Haemoglobin estimation	X
Serum protein level	...
Serum iron	...
Serum bilirubin	...
Other (specify)	...

4.5.2 Biological

Syphilis	X
Hepatitis B	.X.
Malaria	...
AIDS	...

4.6 Transmissible disease among donors (state their frequency):

4.6.1 Hepatitis B X

4.6.2 Malaria X

4.6.3 Other parasitoses (specify)

4.6.4 AIDS

4.6.5 Others (specify)

5. Production of non-stable (cellular) derivatives

5.1 Indicate for the following products the quantities collected/prepared and used:

	Collected/Prepared	Used
5.1.1 Whole blood	171,015	Acute blood loss Exchange H.D.N.*
5.1.2 Red cell concentrate	25,526	Increase patient red cell mass
5.1.3 Frozen fresh plasma	24,008	Coagulation disorder
5.1.4 Dry plasma	1,160	Burn, blood volume expansion
5.1.5 Platelet concentrate	16,014	Bleeding due to Thombocytopenia
5.1.6 White cell concentrate	2,081	Agranulocytosis
5.1.7 Others	29,221	

5.2 Indicate the imported and exported quantities of the above mentioned products and the origin of the imports.

6. Production of stable derivatives

6.1 Indicate for the following products the quantities produced and used: (all hospitals).

	Proposed	Used(approx)
6.1.1 Albumin (including PPF or SPPS)	Just beginning	
6.1.2 Factor VIII		
6.1.3 Factor IX		
6.1.4 Immunoglobulins (a) Normal (b) Specific		
6.1.5 Other		

6.2 Indicate the imported and exported quantities of the abovementioned products and the origin of the imports.

-

6.3 Quantity of plasma collected annually. 500 litres (1984)

6.4 Quantity of plasma fractionated annually and by whom.
Just beginning by National Blood Centre Thai Red Cross Society

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* Haemolytic disease of the newborn

7. Reagents used in immunohaematology

7.1 Indicate the type of reagents and the quantities used annually.
1984: anti-A, anti-B, anti-A,B, anti-D, anti-H, anti-M, anti-N, AHG, other rare antisera

7.2 Indicate the quantities of these reagents produced in the country by type and volume, e.g. anti-A typing serum 50 litres, etc.
anti-A 115, anti-B 120, anti-A,B 54 litres.

7.3 Indicate the serological assessment which blood donors undergo and the origin of the reagents used.
ABO grouping (National Blood Centre) Rh typing (Commercial Company).

7.4 Indicate serological assessment which recipients undergo and the origin of the reagents used.
ABO grouping reagent supply by National Blood Centre

8. Use of blood and blood products

Describe briefly the regulations in effect in the country regarding the use of the principal products.

8.1 Who are the major distributors and users of blood products for diagnosis and therapy?
National Blood Centre, Thai Red Cross Society is the major distributor of blood and blood products to all the hospitals.

9. Blood transfusion costs

(Include costs incurred by Blood Transfusion Services and Government subsidies where appropriate)

9.1 Gross cost -

9.2 On the basis of total health program costs, indicate the proportion represented by blood transfusion programs. -

10. Treatment of patients suffering from haemophilia

10.1 Indicate the products used in the treatment of patients suffering from haemophilia.
The products used in the treatment of patients suffering from Haemophilia are cryoprecipitate

10.2 Indicate the annual cost of the treatment of patients suffering from haemophilia.

11. Bases of co-operation

Indicate your country's requirements with respect to blood derivatives and any interest that may exist in co-operation with other countries in this area.

National Blood Centre is starting plasma fractionation this year and we need transferring of technology from other countries.

12. Projects of the country

12.1 Indicate the country's projects in the area of blood donation

1. Set up the goal to have voluntary non remunerated donors all through the country

2. Supply and produce blood derivatives

12.2 Indicate any projects the country may have, at the national or regional level, regarding industrial blood-fractionation facilities

A small scale of blood fractionation is set up at the National Blood Centre

SUPPLY OF BLOOD & BLOOD PRODUCTS QUESTIONNAIRE*

1. Name of country Thailand

2. Population

   (a) Total 50.5 millions

   (b) % living in major cities & regional centres = 10% (5,000,000)
   (numbers ≥50,000/centre)

   (c) % rural dwellers 90%

3. Describe briefly existing blood transfusion services

   (a) Centralised blood banks
   National Blood Centre, Thai Red Cross Society

   (b) Hospital-based blood banks
   1. National Blood Centre, Thai Red Cross Society.
   2. Chulalongkorn Hospital, (1,236 beds) by the Thai Red Cross Society.
   3. Ramathibodi Hospital (685 beds): Blood Banks and Immunohematology Lab, under the Office University Affairs.
   4. Siriraj Hospital, (1,940 beds), under the Office of University Affairs.
   5. Rajavithi Hospital (846 beds): Blood Bank and Pathology Section, operated by the Medical Service Department (MSD) Ministry of Public Health.
   6. Children's Hospital (538 beds): by the MSD.
   7. Lerdsin Hospital (470 beds): by the MSD.
   8. Vachira Hospital (727 beds): by the Bangkok Metropolitan Administration (BMA).
   9. Central Hospital (246 beds): by the BMA.
   10. Pramongkut-Klao Hospital(Mongkut)
   (1,200 beds) an army based hospital
   11. Pra-Pin-Klao Hospital (523 beds) a navy based hospital.
   12. Phumipol Hospital (700 beds) an air force based hospital.

   (c) Mobile blood collection services
   Performed by National Blood Centre, Thai Red Cross Society

   (d) Regional distribution networks
   Regional branches of National Blood Centre are operated by the Chairman of the Red Cross of the provincial chapters.
   Altogether there are 101 Chapters involved.

   (e) Other - BMA(Bangkok Metropolitan Administration)

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* Prepared by Department of Medical Services

4. Blood donation

Hospital	4.1 Total No. of donors	4.2 Classification of donors 4.2.1 Voluntary Unpaid donors	4.2.2 Voluntary Paid donors	4.2.3 Professional donors	4.2.4 Replace-ment	(From Red Cross)
Total	687,572	613,624 (+350?)	215	65,154	8,229	(23,867)
Red Cross	600,000	~540,000	-	~60,000(10%)	-	
Siriraj	22,218	19,984	-	2,234	-	(7,477)
Rajavithi	2,093	971	-	-	1,122	(12,096)
Chula	26,369	23,374	-	985	2,010	
Ramathibodi	7,922	3,942	-	-	3,980	
Lerdsin	361	99	25	-	237	(4,294)
Mongkut	19,286	19,099	187	-	-	
Vachira	2,069	1,308	-	-	761	
Police	650	59	3	585	3	
Pra-Pin-Glao	4,854	4,788	-	-	66	
Central	350					
Phumpipol	1,400			1,350	50	

4.3 How many donations are collected annually and used as:

Hospital/ Center	(a) Whole Blood (Unit)	(b) Red cell concentrates	(c) Plasma (litres)
Total	246,346	61,143	6,322
Red Cross	171,015	25,526	2,000
Siriraj	29,996	9,716	39.0
Rajavithi	1,624	469	87.4
Chula	12,210	14,142	2,100
Ramathibodi	2,863	5,059	1,011.8
Lerdsin	3,203	1,452	100
Mongkut	17,854	1,432	460+
Vachira	2,069	-	-
Police	377	-	-
Pra-Pin-Glao	550	-	-
Children's	2,855	3,097	313.8
Central	330	-	-
Phumipol	1,400	250	150

+ 173.6 Lt from Red Cross

4.4 Which of the following organisations are responsible for blood collection in your country? Indicate percentage that each contributes to the overall collection.

4.4.1 National funded and controlled blood banks 10 %

4.4.2 Blood banks belonging to other organizations 90 % (Red Cross)

4.4.3 Commercial blood banks

4.4.4 Others

5. Production of non-stable (cellular) derivatives

5.1 Indicate for the following products the quantities collected/prepared and used: (Unit)

	5.1.1 Whole Blood		5.1.2 Red Cell Concentrated		5.1.3 Frozen Fresh Plasma		5.1.4 Dry Plasma	
	Collected /Prepared	Used	Collected /Prepared	Used	Collected /Prepared	Used	Collected /Prepared	Used
Total		73,536		40,739		17,702	1,160	-
Red Cross	171,015		25,526		24,008		1,160	
Siriraj	19,984	29,996	9,716	9,716	3,728	3,592	-	
Rajavithi	2,093	10,213	-	3,838	-	1,114	-	-
	/1,624		/ 469		/ 414			
Chula	12,210	7,908	14,142	10,950	5,122	5,115	-	-
	/12,911		/11,315		/5,122			
Rimathibodi	2,863	6,846	5,059	9,111	5,059	4,488	-	-
Lerdsin	5,708	4,655	-	1,452	-	107	-	-
Mongkut	18,426	-	673	-	611	-	-	-
Vachira	2,069	6,426	914	1,413	644	747	-	-
Police								
Pra-Pin-Glao	500	550	250	250	880	880	-	-
Central	330	2,889	-	662	-	40	-	-
Children	-	2,855	-	3,097	-	1,569	-	-
Phumipol	1,800	1,200	300	250	70	50	-	-

(Cont..)

	5.1.5 Platelet Concentrate		5.1.6 White Cell Concentrate		5.1.7 Others Fresh Plasma	
	Collected /Prepared	Used	Collected /Prepared	Used	Collected /Prepared	Used
Total		14,608		2,343		19,832
					/155	
Red Cross	16,014		2,081		29,221	
Siriraj	4,500	4,313	12	12	5,291	5,273*
Rajavithi	-	1,309	-	64	-	1,323
	/105				/ 155	
Chula	2,141	2,120	7	7	-	
	/2,141		/7		-	
Ramathibodi	2,909	5,814	1,415	1,962	1,671	8,308+
					1,671	4,107++
Lerdsin	-	214	-	-		735*
Mongkut	398	-	31	-	-	-
Vachira	109	185	29	177	4	4
Police						
Pra-Pin-Glao	300	300	30	30	2	2
Central	-	40	-	-	-	-
Children	-	298	-	53	-	
Phumipol	15	15	38	38	100	80*

+ Cryoprecipitate

++ Cryoremoved plasma

* Aged plasma

6. Production of stable derivatives

6.1 Indicate for the following products the quantities produced and used.

		Proposed	Used
6.1.1	Albumin (including PPF or SPPS)		
	PPF	Just beginning (Red Cross)	152,850 cc (Siriraj)
	SPPS		
6.1.2	Factor VIII	Yes	Yes (Chula)
6.1.3	Factor IX	-	-
6.1.4	Immunoglobulins	-	-
	(a) Normal	-	-
	(b) Specific	-	-
6.1.5	Others	-	-

6.2 Indicate the imported and exported quantities of the abovementioned products and origin of the imports.

6.3 Quantity of plasma collected annually.

Red Cross	500 Lt	Vachira	191 Lt.
Chula	125 Lt	Phumipol	408 Lt. (2040 Units)
Central	33.4 Lt (167 Units)		

6.4 Quantity of plasma fractionated annually and by whom.

- Just beginning by National Blood Center Thai Red Cross Society
- National blood bank of Thai Red Cross

	Total	Red Cross	Siri raj	Raja vithi	Chula	Rama-thibode	Lerdsin	Mong kut	Vachi ra	Central
Anti A	133,824	115,000	2,700	3,684	~3,000	~7,200	400		1,340	500
Anti B	141,128	120,000	5,100	3,588	~3,000	~7,200	400		1,340	500
Anti AB	70,394	54,000	4,650	3,144	-	7,200	400		500	500
Anti A_1	5,270	-	5,250	20	-	-	-		-	-
Anti D	3,900	-	1,000	10	~1,700	-	300		890	-
Anti H	400	-	-	400	-	-	-		-	-
Coombs reagents	21,824	-	9,000	5,984	-	~4,000	350		1,490	1,000
Anti HB_sAg	3,292	-	-	200	-	-	-		3,092	-
Albumin	5,500	-	5,000	-	-	-	-		-	500
Enzyme eg										
Papain	12,000	-	9,600	2,400	-	-	-		-	-
N.S.S.	1,857,600	-	57,600	1,800,000	-	-	-		-	-
PBS	36,000	-	28,000	8,000	-	-	-		-	-

Rare Red Cell antibodies e.g. Anti H, Anti c Anti C, Anti E, Anti e, Anti M, Anti N, Anti Mi^a Anti P_1, Anti Jk^a Anti Jk^b Anti K Anti Fy^a Anti Fy^b Anti Le^a Anti Le^b Anti Le^a + Le^b Anti Lu^a Anti Lu^b Anti S Anti s Anti Di^a Anti Di^b

HLA Antisera for HLA - A , B, Cw and DR (Siriraj Only)

1984 - Anti - A, Anti - B, Anti A,B, Anti - D, Anti - H, AHG, Other rare antisera
Note: Thai Red Cross

7.2 Indicate the quantities of these reagents produced in the country by type and volume.

Anti - A 115, anti B 120, anti-AB 54 litres.

7.3 Indicate the serological assessment which blood donors undergo and the origin of the reagents used.

7.3.1 ABO grouping - Direct

- Reverse

Anti D typing

Antibody screening & Identification

VDRL

HB_sAg

7.3.2

Anti A	National Blood Center Thai Red Cross
Anti B	" "
Anti AB	" "
Anti A_1	" "
Anti H	" "
Coombs Reagent S.	" "
Std A,B Cells Screen C Cells	Local made (Siriraj Hospital)
RH typing	Commercial Company
Anti D	Biolabs New zealand, Crtho Diagnostic U.S.A. General Diagnostic U.S.A.
Anti HB_sAg	Behring Germany

(Note : from Rajavithi and Siriraj Hospital)

ABO grouping (National Blood Centre)

Rh typing (Comercial Company)

(Note : from Red Cross)

7.4 Indicate serological assessment which recipients underro and the origin of the reagents used.

ABC grouping - Direct (Supply by National blood centre)

- Reverse

Antibody D typing

Antibody screening & Identification test

Cross Matching

Anti A

Anti B

Anti AB

Anti D Biolabs Newzealand and Orths Diagnostic U.S.A.

Coombs Reagents " " "

and General Diagnostic U.S.A.

Enzyme Papain B.D.H.

One stags and two stage technique

Albumin

8. Use of blood and blood products. National Blood Centre

Describe briefly the regulations in effect in the country regarding the use of the principal products

8.1 Physicians, hematologists

9. Blood transfusion costs
(Include costs incurred by Blood Transfusion Services and Government subsidies where appropriate)

9.1 Gross cost = 5,636,362 baht from Siriraj Hospital
(Blood is given free of charges, however service charges are varied by hospitals approximately 60-100 baht/unit.)

10. Treatment of patients suffering from haemophilia

10.1 Indicate the products used in the treatment of patients suffering from haemophilia.

FFP*	4510 units/year
F VIII (cryo)	3838 units/year

(from Chula Hospital)

10.2 Indicate the annual cost of the treatment of patients suffering from haemophilia.

1. FFP 451,000 baht
   F VIII (cryo) 383,800 baht
2. or a total of 834,800 baht by Chula hospital
3. a total of 540,000 baht per year by 118 cases is Siriraj Hospital.
4. a total of 10,000 baht in Children's Hospital.

11. Bases of co-operation
Indicate your country's requirements with respect to blood derivatives and any interest that may exist in co-operation with other countries in this area.

National Blood Centre is starting plasma fractionation this year and needs transferring of technology from other countries.

Ramathibodi: The co-operation should be directed to the decrement of imported reagents and equipments such as biological test for AIDS and blood packs.

* Fresh Frozen Plasma

12. Projects of the country

12.1 Indicate the country's projects in the area of blood donation

1. Set up the goal to have voluntary non-remunerated donors all through the country.
2. Supply and produce blood derivatives

12.2 Indicate any projects the country may have, at the national or regional level, regarding industrial blood-fractionation facilities

A small scale of blood fractionation is set up at the National Blood Centre.

(No.12 Commented by the National Blood Centre).

APPENDIX 6

Siriraj Hospital: Statistical Summary (1980 - 1984)

	1980	1981	1982	1983	1984
1. Donor (unit/year)					
Professional	3,886	2,537	2,406	2,325	2,234
Red Cross	11,418	10,532	9,177	9,550	7,477
Replacement	6,480	8,382	9,573	11,084	10,377
Voluntary	3,858	5,452	8,048	7,694	9,607
Total	25,642	26,903	29,204	30,653	29,695
2. Blood Component (unit/year)					
Packed red cell	7,752	8,010	9,713	8,974	9,716
Fresh Frozen Plasma	3,068	3,485	3,887	3,969	3,728
Cryoprecipitate A.H.G.	2,376	3,671	4,350	4,780	5,291
Platelet Concentrate	2,782	3,678	4,145	4,081	4,500
Leukocyte Depleted Blood	224	150	141	154	106
Plasma	838	474	1,604	2,474	2,561
Thrombocytapheresis	38	62	30	12	13
Leukapheresis	-	10	25	34	12
Plasmapheresis	-	12	13	4	2
3. Transfusion Request (case/year)	22,544	22,683	25,029	25,826	26,280
4. Cross-matching (case/year)	52,282	52,465	59,907	63,964	63,792
5. Coombs Test (case/year)					
Direct	1,957	2,249	2,954	2,534	2,104
Indirect	1,903	2,212	2,846	2,380	1,922
6. Blood Grouping (case/year)	592	543	466	483	490
7. Antibody Screening (case/year)	36,768	39,054	45,056	46,929	48,498
8. Antibody Identification (case/year)	2,188	2,645	2,343	1,886	2,045
9. HBsAg Screening (case/year)	19,099	19,462	21,526	25,013	23,000
10. HLA Typing (case/year)	295	272	159	190	332
11. Ab. Screening (case/year)	1,909	10,144	52,323	126,080	108,432
12. Outdated Blood (unit/year)	428	330	470	429	507
13. Frozen Blood (unit/year)	-	2	8	1	2
14. Cross matching for platelet (unit/year)	27	105	86	79	83

THE PHILIPPINES

In Manila, I met with representatives of the Philippine National Red Cross, the Ministry of Health and with haematologists in both public and private practice.

My discussions with the Philippine Red Cross Society were held with Dr. G. Caridad, Secretary-General and Dr. C. Samson, Director of the National Blood Programme. The Red Cross collects blood from voluntary donors only and although it operates nationally, is responsible for only some 50-60 percent of the total blood used in the country. A large number of Red Cross donations continue to be taken into single 300 mL packs although there is an active programme to phase this practice out and to adopt the 430 mL donation as standard for the future. In addition to the national centre in Manila, the Red Cross operates three other regional blood centres which recruit donors, collect, process and prepare blood components as well as preserving blood and distributing it to patients. They also run 31 provincial blood centres throughout the country which are equipped to collect, process, store and issue blood. Two blood mobiles based on the national centre are used in metro Manila to collect blood from large industrial organisations, universities, etc. The Red Cross currently collects about 100,000 blood donations annually. They find, however, that the demand for blood considerably exceeds this figure and there is never enough blood to cope with the ever increasing requirement of a country with a population of 52 million.

The majority of the larger hospitals in the greater Manila area have their own blood banks whose donors are usually professionals. However, most of their indigent patients request blood from the Red Cross because they cannot afford to pay the prices charged for bought blood (of the order of 120 pesos per unit exclusive of testing costs). Commercial for profit blood banks are also to be found in metro Manila and in the provinces.

Very little of the blood collected by the Red Cross is processed to components; the amount of packed cells issued in 1984 was less than three percent of the total collected. The reasons for this are -

a) that they cannot keep up with the demand for whole blood; and

b) the cost of double and triple packs which the Red Cross just cannot afford to buy.

They receive no subsidy from the Government and the small processing fee that they charge certainly does not cover their actual costs. The only way in which they can expand their collection and component preparation programmes is for the Society to allocate more funds to the Blood Transfusion Service. This in turn is contingent upon raising extra funds from public appeals which is an unlikely scenario given the current economic conditions.

They routinely screen donors for haemoglobin levels and donations for evidence of syphilis but have not instituted HBsAg testing because of the cost involved. Some 10-15 percent of the population are carriers but as 50-60 percent have antibody, they reason that antigen positive donations will do little harm to patients who are already immune. Because the hospitals have legal responsiblity for the safety of the blood administered, they routinely check for antigen before

the material is given to patients. The Red Cross does not produce its own blood typing sera but relies on commercial sources for these reagents.

Because of a current shortage of blood and its components, the Society proposes to intensify blood donor recruitment activities so that the total number of units collected can be increased. They hope to set up new chapter blood centres to acquire new blood mobiles and equipment required for component preparation and to optimise the use of collected blood by increasing the production of stable components and educating the medical profession on the benefits of component therapy.

From Dr. Basaca-Sevilla, Director, Bureau of Research and Laboratories, Ministry of Health, I learnt that the Government is responsible for the licensing of all blood banks that operate in the country. In addition to the Red Cross establishments already mentioned, there are 156 licensed blood banks made up as follows -

	HOSPITAL BLOOD BANKS		COMMERCIAL	TOTAL
	Government	Private		
Metro Manila	10	21	15	46
Provinces	44	56	10	110
Total	54	77	25	156

Thus, while the Government is responsible for the licensing of all blood banks it is directly responsible for the running of only approximately one-third, ie those associated with Government hospitals. While it is official policy to encourage voluntary blood donation and to seek replacement donors from among a patient's relatives, a significant amount of blood is still supplied by commercial blood banks in single plastic packs. Thus, in 1984, for example, over 150,000 donations were produced by the nine major commercial blood banks in metro Manila alone.

Efforts are being made to increase the acceptance of components but progress is slow. The first priority must be to increase overall collection to eliminate the shortage of whole blood and to better educate clinicians so that they no longer insist on fresh blood or administer single unit transfusions. The Government cannot afford to underwrite the cost of special plasma collection programmes, eg by paying for double packs or for tests required prior to plasma fractionation, eg screening for HBsAg. The latter costs 12,000 pesos per 1000 tests and the Bureau was offering this service but had to suspend it since the budget has been frozen at 1982 levels.

I also met with officers of the Philippine Society of Haematology and Blood Transfusion and with the Acting President of the Philippine Blood Coordinating Council. These four doctors were able to represent the views of the major users of blood and blood products in metro Manila.

It was agreed that there is a legitimate need for Albumin which is not being met because patients cannot afford to pay for it. It is also difficult to obtain as drug companies generally do not hold stock. Small quantities are purchased through US military bases in the Philippines at $US50 per 25 grams - a price that is probably subsidised. Patients in shock are usually managed with blood when available, saline and artificial plasma volume expanders.

Haemophilia A is not a common clinical problem and all cases can be managed with a combination of cryoprecipitate and fresh frozen plasma. They probably see more patients with Factor IX deficiency and children with acquired prothrombin complex deficiency syndrome. The latter two groups are managed with fresh frozen plasma. There is an increasing demand for platelets but by far the commonest haematologic abnormality is iron deficiency anaemia of dietary origin. This is being combated with nutritional education programmes and foods fortified with additional iron.

In a few hospitals the usage of packed cells has risen steadily from a base level of approximately ten percent to current levels of 40-50 percent. There was a feeling that this trend could be expanded to include other centres and that if double or triple plastic packs could be made available for the collection of the blood, several thousand litres of plasma per annum could be produced to yield Albumin and other fractionated products to which at present they scarcely have access. There is also a need for Fibrinogen (this can possibly be met by the use of cryoprecipitate) and certain specific Immunoglobulins particularly Tetanus, Rabies and Hepatitis B.

All present expressed the view that many of their patients could be managed better if they had access to a wider range of fractionated blood products and were keen to extol the virtues of component therapy to their colleagues in the expectation that surplus plasma could be fractionated to yield needed products at reasonable costs.

I also visited the Makati Med Centre, one of the largest private hospitals in metro Manila where I had discussions with Dr. Garcia and Ms Medenilla. The hospital has 550 beds and they collect some 500-600 units of blood every month. Most of this is used as whole blood for emergency and routine surgical cases but they also prepare packed cells, cryoprecipitate and fresh frozen plasma. In addition, they provide this service to other hospitals in the area who are not equipped to produce their own blood components. Although they encourage voluntary donation they find it is very difficult to persuade donors or relatives of patients to give their blood voluntarily. The latter will often prefer to pay for blood obtained from professional donors rather than give blood themselves. Again, fractionated products are rarely ordered because of their high cost even though this is a private centre in which patients must pay for all the services provided. They do run an indigent care programme under which patients who cannot afford to pay for the treatment are looked after at nominal cost.

SUPPLY OF BLOOD & BLOOD PRODUCTS QUESTIONNAIRE

1. Name of country Philippines

2. Population

   (a) Total 52 million

   (b) % living in major cities & regional centres (numbers $\geq$50,000/centre)

   (c) % rural dwellers 78 %

3. Describe briefly existing blood transfusion services

   (a) Centralised blood banks
   The PNRC*has a National Blood Center that oversees the administrative and operational machinery of its regional and provincial blood centers.
   It undertakes donor recruitment, screening of conors, collection, processing and dispensing of human blood and components.

   (b) Hospital-based blood banks
   Majority of hospitals in the Greater Manila area have their own blood banks. Blood donors are usually professionals. However, most of their indigent patients request blood also from the Red Cross.

   (c) Mobile blood collection services
   Only the Red Cross is involved in mobile blood collection. Our National Blood Center has 2 bloodmobiles equipped with refrigerators for field donations. One of these has two beds where donors can be bled. In all other cases, vehicles transports blood collection personnel and equipments to designated areas of donor session.

   (d) Regional distribution networks
   The Red Cross has three regional blood centers established in strategic areas to service blood needs of their respective regions. These regional blood centers are tasked to enlist donors, collect, process and prepare blood components, preserve and distribute blood to patients. At present we have 31 provincial chapter blood centers manned and equipped with facilities for blood collection, processing and storage and dispensing of collected blood.

   (e) Other
   There are several commercial blood centers in the Metro Manila that are operating with some outlets in the provinces.

4. Blood donation

   4.1 Total number of donors = Red Cross only - 100,000 units average annually

   4.2 Classification of donors

   4.2.1 Number of voluntary unpaid donors = all Red Cross donors

   4.2.2 Number of voluntary paid donors = hospital blood banks

   4.2.3 Number of professional donors all commercial blood bank donors

   4.2.4 Others

---

* Philippine National Red Cross

4.3 How many donations are collected annually and used as:
(a) whole blood = 89,295 collected; 78,277 used

(b) red cell concentrates = 2,863

(c) plasma (give volume in litres).= 500 liters more or less.

If plasma is obtained other than as a by-product of red cell concentrates e.g. by plasmaphereses, indicate the additional volume collected annually (in litres).

4.4 Which of the following organisations are responsible for blood collection in your country? Indicate percentage that each contributes to the overall collection.

4.4.1 Nationally funded an controlled blood banks	% None
4.4.2 Blood banks belonging to other organisations e.g. Red Cross 60% Red Cross only	%_____
4.4.3 Commercial blood banks	%40
4.4.4 Others	%_____

4.5 List the biomedical tests performed on donors (please tick)

4.5.1 Chemical

Haemoglobin estimation	X
Serum protein level	...
Serum iron	...
Serum bilirubin	...
Other (specify)	...

4.5.2 Biological

Syphilis	X
Hepatitis B	...
Malaria	...
AIDS	...

4.6 Transmissible disease among donors (state their frequency):
4.6.1 Hepatitis B

4.6.2 Malaria

4.6.3 Other parasitoses (specify)

4.6.4 AIDS

4.6.5 Others (specify)

5. Production of non-stable (cellular) derivatives

5.1 Indicate for the following products the quantities collected/prepared and used:

	Collected/Prepared	Used
5.1.1 Whole blood	89,295	78,277
5.1.2 Red cell concentrate	2,863	2,333
5.1.3 Frozen fresh plasma	507	399
5.1.4 Dry plasma	none	
5.1.5 Platelet concentrate	1,327	1,296
5.1.6 White cell concentrate (Buffy Coat)	7	7
5.1.7 Others-cryoprecipitate	111	88
Wet plasma	2,257	1,230

5.2 Indicate the imported and exported quantities of the above mentioned products and the origin of the imports.

NONE

6. Production of stable derivatives

6.1 Indicate for the following products the quantities produced and used: (all hospitals).

		Proposed	Used
6.1.1	Albumin (including PPF or SPPS)	none locally	no statistics available
6.1.2	Factor VIII		
6.1.3	Factor IX		
6.1.4	Immunoglobulins (a) Normal (b) Specific		
6.1.5	Other		

6.2 Indicate the imported and exported quantities of the abovementioned products and the origin of the imports.

Above product if available are distributed by commercial pharmaceutical firms purchased from abroad.

6.3 Quantity of plasma collected annually. none

6.4 Quantity of plasma fractionated annually and by whom.
none

7. Reagents used in immunohaematology

7.1 Indicate the type of reagents and the quantities used annually.
Blood Grouping sera = 1,000 sets annually.
VDRL Antigen = 400 Anti-D = 100 vials

7.2 Indicate the quantities of these reagents produced in the country by type and volume, e.g. anti-A typing serum 50 litres, etc.
none.

7.3 Indicate the serological assessment which blood donors undergo and the origin of the reagents used.
VDRL - USA.
Grouping Sera - Frankfurt, West Germany.

7.4 Indicate serological assessment which recipients undergo and the origin of the reagents used
No data

8. Use of blood and blood products

Describe briefly the regulations in effect in the country regarding the use of the principal products.
The collection, processing and sale of human blood and the establishment and operation of blood banks and Blood Processing laboratories is governed by Republic Act 1517 of Philippine Congress.

8.1 Who are the major distributors and users of blood products for diagnosis and therapy?
The major distributors of blood and products are Red Cross Blood Centers and commercial blood banks. The users of blood products for therapy are mostly the Metropolitan hospitals.

9. Blood transfusion costs

(Include costs incurred by Blood Transfusion Services and Government subsidies where appropriate)

9.1 Gross cost = Red Cross only - 5,000,000.00

9.2 On the basis of total health program costs, indicate the proportion represented by blood transfusion programs.
no data

10. Treatment of patients suffering from haemophilia

10.1 Indicate the products used in the treatment of patients suffering from haemophilia.
Cryoprecipitate and fresh frozen plasma

10.2 Indicate the annual cost of the treatment of patients suffering from haemophilia.
No data

11. Bases of co-operation

Indicate your country's requirements with respect to blood derivatives and any interest that may exist in co-operation with other countries in this area.

None

12. Projects of the country

12.1 Indicate the country's projects in the area of blood donation

By Red Cross -

1. To increase blood collection output
2. To set up new chapter blood centers
3. To acquire new bloodmobile and equipments
4. To maximize the use of collected blood by increased production of stable components, train staff, and educate medical group on component therapy.
5. To intensify blood donor recruitment activities.

12.2 Indicate any projects the country may have, at the national or regional level, regarding industrial blood-fractionation facilities

None

DISCUSSION AND RECOMMENDATIONS

DISCUSSION

The foregoing observations can best be summarised as follows. Taken overall, current supplies of blood are at best marginal. Collection rates vary from 5-20 per 1000 of the population which is barely sufficient to meet current needs. In fact, when one considers that the majority of donations are collected in major urban centres while, with the exception of Singapore, most of the population lives in rural areas then it must be conceded that the present availability of blood does not meet the region's needs.

These comments apply to whole blood. The difficulty of motivating and recruiting new donors was pointed out to me time and again. The situation is even worse when one looks at the availability of components. I use the term here to designate derivatives of whole blood that can be prepared by a reasonably well equipped blood bank; concentrated red cells, cryoprecipitate, platelet concentrates and fresh frozen plasma in particular. The need for component therapy is well recognised by both Transfusion Service and hospital blood bank staff. Not only does it enable the patient to receive the specific treatment that he requires but by allowing the production of a number of products from the one donation it allows the maximum utilisation of a precious human resource.

The increased utilisation of components is being frustrated for two main reasons -

a) There is a reluctance on the part of clinicians, particularly the older ones, to use products they are not accustomed to. Thus, there is still an irrational demand for fresh whole blood and a disinclination to use packed cells. This is an educational problem common to developed as well developing countries that can be overcome by updated undergraduate teaching, by post graduate refresher courses, by appointment of transfusion officers with the necessary status and authority to discuss individual cases with clinicians and by the introduction of blood audits at least in teaching hospitals.

b) The second problem is an economic one. To prepare components in a closed system one needs to have access to double, triple or quadruple plastic packs. Although considered consumables, these items are not cheap and form a considerable part of any blood bank's budget. Nevertheless, they are essential both for the reason mentioned here and if plasma is to be made available for more sophisticated fractionation and means will have to be found to make them more affordable. I shall return to this problem later.

Are current demands being met? This is a difficult question to answer because it depends on whom one asks! With the possible exception of Singapore which only needs to provide for a small population of 2.5 million people, the other ASEAN countries all need more of everything - whole blood, components and fractionated products. This

was certainly the message I got from all the clinicians to whom I spoke. While appreciative of the efforts of major blood collection agencies in their country (national, Red Cross, regional, local), they all felt that patient care could be improved if more blood was provided and if they have access to products such as Albumin, clotting factors and certain immunoglobulins. The latter fractionated products must presently be imported and the costs are so high that they are rarely if ever ordered. I suspect that the real need for such products is greater than haematology and other specialists estimate since many patients who could benefit from their use are never referred because of the virtual impossibility of obtaining supplies.

"Legitimate demand" must, of course, be clearly defined. It does not equate with meeting every request that the clinician makes but there needs to be continuing dialogue between producers and users so that scarce resources are not squandered and priorities are defined to everyone's satisfaction.

There is no reason to suspect that the need for blood products in the ASEAN countries is any less than that in developed countries. Indeed, the opposite may be true when one considers the burden of such clinical conditions as thalassaemia and acquired hypofibrinogenaemia due to snake bite.

The need for improved supplies of blood and blood products is well recognised; indeed, it has been known for many years. What needs to be done to remedy the situation?

1. Blood Supply

All the countries that I visited have good national blood collection systems with adequate decentralisation often supplemented by mobile and hospital based collections as well. The basic reason why blood collection rates are low by world standards appears to be a cultural one - people are just not conditioned to the need to give blood. Community attitudes need to change and this will require a widespread and long term educational programme starting in the schools and continuing for all age groups with the assistance of community based organisations such as the Red Cross and Red Crescent Societies, Rotary, etc.

Ideally, blood should be given on a voluntary basis. This is in keeping with the WHO resolution of 1975 and is the practice being adopted in most countries. Purchased blood is often obtained from the indigent poor who for reasons of poor nutrition are less able to afford the loss of protein and iron than their compatriates who are better off.

All those to whom I spoke where blood is still being purchased would prefer the practice to cease. In reality, however, the system would collapse if this were to happen overnight and the two systems would need to co-exist until enough new voluntary donors can be recruited to make up the shortfall.

The collection of increasing amounts of blood is not only necessary to meet current shortfalls but is of course essential in any consideration of a plasma fractionation programme irrespective of the scale or where it is carried out. If fractions are to be produced locally for use in the region there will be a need to provide additional plasma for this purpose probably by a combination of increasing the percentage of blood that is turned into components at the point of collection and by again boosting the total number of donations taken, ie increasing the donor panel. The cost implications of both steps are obvious.

2. Plasma Fractionation

For the purpose of this discussion, I have assumed that it is intended to set up a fractionation facility somewhere in the ASEAN region. It is not important at the moment to decide what type of plant or where it may be situated. I merely want to draw attention to the commitment that will need to be made and to the minimum requirements covering such aspects as plasma quality, access to raw materials and services, staff training and quality assurance.

a) Plasma Quality. To obtain sterile product of good quality and potency it is essential that the starting plasma be of the highest quality whether collected as fresh plasma for clotting factor production, as outdated plasma for Albumin or as plasma with specific levels of certain antibodies for high titre immunoglobulins. Plasma needs to be tested for freedom from HBsAg, procedures used must ensure minimal or zero bacterial contamination and the material must be handled, transported and stored to ensure minimal deterioration and alteration of the many components of which it is made up. Careful labelling, packaging and documentation also form an essential part of the quality validation of this vital source material.

b) Raw Materials and Services. Beside plasma, admittedly the major feedstock, there are other raw materials that need to be considered when one is planning a fractionation plant. These include distilled and deionised water, alcohol, process buffers, certain chemicals and formulation ingredients. Since fractionated plasma products are no different from other pharmaceuticals, codes of good manufacturing practice (GMP) must be observed in their manufacture including validation of all raw materials before they are employed in the process.

Good support systems are also an essential feature of a successful fractionation plant. Large quantities of pure water are needed as are high quality steam, compressed air, autoclaves and clean filling areas.

c) Staff Training and Quality Assurance. The expertise required for this industry is best attained with the help of a sponsor organisation, ie an experienced fractionator who cannot only train staff for the necessary tasks that have to be performed but should also be involved in the design and construction phases of any new facility on a consultant basis. The involvement of Government control authorities with responsibility in this field at the very earliest stage is also essential to minimise costly delays.

Quality assurance is essential at each stage of the process - from the bleeding of the donor to the testing of the final packaged product. Again, suitable staff for training in this area should be selected and seconded to the relevant sponsor organisation. The period of expatriate training should also include some time spent in the laboratories of the relevant national control authority.

3. Cost Benefit Analysis

It is not the purpose of this preliminary survey to make a detailed analysis of capital and recurrent costs that would be incurred in setting up a plasma fractionation plant in the ASEAN region. There are, at this stage, too many variables and unknowns to make this a useful exercise. Nevertheless, the questions I have listed below and undoubtedly others will need to be addressed before a "go/no go" decision can be made, for example -

i) What type of plant (Cohn, chromatographic, hybrid, etc)?

ii) Capacity - (a) initial, (b) eventual?

iii) Location?

iv) Costs to design and construct?

v) Annual operating costs?

vi) The mix of products and their prices to the clients (member governments)?

vii) What is the break even point in terms of annual ouput?

viii) What additional burdens will be placed on health budgets and are they acceptable?

4. Matters Requiring Further Study

There seems to be universal agreement among those with whom I had discussions that improvement in the supply of blood fractions (and in certain instances blood itself) is needed. If this is accepted, there needs to be a closer examination of the following aspects -

a) Can the region justify the establishment of a plasma fractionation facility? The combined population of the ASEAN countries exceeds that of North America. As the latter currently supports several large fractionation plants there is no doubt in my mind that eventually more than one plant will be needed to cater for the needs of South-East Asia.

b) Can adequate supplies of good quality plasma be guaranteed? This, of course, is the nub of the problem and at the moment the answer is no. At least three of the five countries would find it almost impossible to provide plasma that is additional to their present capacity. The reasons for this I have outlined above.

If the project is to get off the ground then ways must be found to remove existing barriers, eg funds will be needed to mount donor recruitment programmes and for the purchase of additional multiple plastic packs. The possible price advantage of standardising requirements and bulk purchasing should be considered and even the eventual establishment of a pack manufacturing plant in the region.

c) Are suitable staff available to run such a plant? I met with very experienced blood transfusion service personnel who have a knowledge of what is required. A regional or for that matter a national fractionation plant would be additional to existing requirements. It would therefore require the selection and training of suitable staff from the Director/Manager down and their secondment to one or more overseas establishments for periods varying from six months to two years. Training programmes will have to be tailored to the individual's projected responsibility. Apart from the scientific and technical staff needed for the day to day operation, it is vital to employ good maintenance engineers who will supervise the equipment and services and will be capable of carrying out repairs should this prove necessary. Down time must be kept to an absolute minimum.

d) Can the costs be justified? No attempt has been made in this Phase 1 survey to cost any aspect of the proposal. It is relatively simple to calculate the capital and running costs if we assume for a moment that the project might be commenced by building a classical Cohn plant with a capacity of 30,000-40,000 litres per annum on a site with good access to services and transportation. That, however, is only part of the total that needs to be considered. Matters such as donor recruitment, more multiple packs, extra refrigerated centrifuges, new freezers, additional staff, etc must all be taken into consideration in computing the total cost. Then the answers must be matched against the cost and availability of product currently purchased, bearing in mind such unquantifiable factors as long delivery lead times and the need for dependency on some other nation's blood collection system. In the final analysis, governments and, in particular, Health Ministries will have to decide what priority to allocate to this unique group of biological drugs as opposed to the multitude of demands that they are subjected to for all areas of the health care spectrum.

RECOMMENDATIONS

In the light of the information furnished to me and the knowledge gained from personal discussions with Transfusion Service Directors, major users of blood products and Health Ministry officials in the ASEAN countries, I recommend -

1. That this report be forwarded to the above for their information and that they be asked for their comments.

2. If a majority agree on the desirability of establishing a fractionation industry in the region, a planning group should be set up under the aegis of UNIDO.

3. Such a group should operate at at least two levels - technical experts and government officals - but there must be close liaison between the groups and they should exchange minutes of meetings and meet jointly when required.

4. Their initial agenda should address itself at least to the matters that I have listed above under the heading of those requiring further study.

5. At least one overseas expert should be invited to participate in the meetings of technical experts. If the more detailed feasibility study that I am now proposing shows that the concept is viable it would be preferable if that overseas expert were from a possible sponsor organisation (see above) but this is not essential.

6. The detailed feasibility study, if approved, must run to a tight schedule. There is much work to be done but one should aim to complete it within 12 months of commencement.

Finally, I should comment on the obvious desire/intent of some countries to set up a fractionation capacity of their own. Thailand has already taken the first tentative steps and they are to be congratulated for their initiative. I see no significant conflict between what I propose, ie a detailed examination of the feasibility of placing a pilot plant somewhere in the ASEAN region and the perceived need of some to establish their own facility. Indeed, there is the opportunity for all to learn from one another for I am certain that more than one plant will be needed to serve the needs of the populations concerned in the fairly near future. What is important is that a start be made and soon.

I was frequently asked how such a project would be funded. This was not part of my brief but as it obviously weighs heavily on the minds of those charged with such matters it needs to be addressed at an early stage. There is little point in carrying out a great deal of careful analytical study only to be told at the end that funds just are not available.

The above comments are general, ie they apply to a greater or lesser degree to the five countries that I visited. It may also be helpful to make specific recommendations pertaining to individual countries.

MALAYSIA

1. The proposed new National Transfusion Centre needs to be established on a site that is central so that donors have easy access and it must be close to its major customers - the larger metropolitan hospitals.

2. The Centre should have adequate space, not only for donors, but also for plasma separation and the preparation of components such as platelets, FFP and cryoprecipitate.

3. Consideration should be given to a suitable career structure for both doctors and scientists working in blood transfusion.

INDONESIA

1. A lack of Government funding is holding back expansion of blood transfusion services. It is important that all donations be screened at least for HBsAg, at the point of collection and that funds be made available to purchase multiple plastic packs so that plasma can be salvaged and better use can be made of component therapy.

2. Further efforts in the area of donor recruitment are urgently required.

THAILAND

1. Clinicians need to be better informed about the importance of component therapy. This will release plasma to produce more cryoprecipitate and other plasma fractions.

2. The donor recruitment programme needs to be reinforced. The assistance of the League of Red Cross Societies should be sought in this area.

THE PHILIPPINES

1. An extensive donor recruitment programme, spearheaded by the Red Cross, is needed urgently.

2. Additional funds are required to purchase plastic packs so that components can be prepared.

3. To achieve 1 & 2 the Government should provide the monies needed. The overall cost will be comparatively moderate, but it is unrealistic to expect to raise it from public donations.

ACKNOWLEDGEMENTS

I would like to thank everyone associated with the planning of my itinerary and particularly those who took the time and trouble to answer the rather detailed questionnaire and to explain to me personally the current situation in their various countries. Without such help it would have been much harder to gain even a preliminary overview of the problems. My thanks also to UNIDO for giving me the opportunity to undertake this mission and to the Commonwealth Serum Laboratories for relieving me of my normal duties to carry it out.